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## **The DCIS Debate: New Study Finds that More Than Half of Women with Under Treated DCIS Recur within Five Years**

### **Researchers Caution Against *Watch and Wait* Philosophy**

#### ***Abstract: Are We Over-Treating Ductal Carcinoma in Situ (DCIS)?***

Dallas, April 14, 2016--More than half of all women with pre-cancerous ductal carcinoma in situ (DCIS) that is inadequately excised will develop a recurrence of the disease or invasive breast cancer within ten years of initial diagnosis, according to a new study presented this week at the Annual Meeting of the American Society of Breast Surgeons.

The study is particularly significant, given the recent high level of media coverage suggesting that current DCIS treatment protocols are overly aggressive and that surveillance alone may be preferable to immediate treatment for women with low-grade DCIS.

“Unlike many recent DCIS studies, we focused on recurrence, not mortality as an endpoint,” comments lead researcher Sadia Khan, D.O., program advisor, Hoag Breast Care Center, Hoag Memorial Hospital Presbyterian, Newport Beach, CA and assistant clinical professor of surgery, Keck School of Medicine, University of Southern California. “With DCIS, we knew mortality would be low. However, recurrence may lead to a more advanced form of breast disease, and potentially more aggressive treatment at a later date. For example, treatment for invasive breast cancer recurrence might include lymph node dissection, extensive radiation or mastectomy, which could significantly lower a woman’s quality of life going forward.”

While Dr. Khan believes that some DCIS may not require the level of treatment typically delivered today, she says that until DCIS recurrence risks can be clearly stratified, this study illustrates that simple surveillance should not be the recommended option. “Given these results, a watch and wait philosophy would be harmful for many women,” she comments.

The study utilized a large prospective database of women with pure DCIS treated with tumor excision alone. The database was contributed by Melvin J. Silverstein, M.D., noted DCIS authority and pioneer of the USC/Van Nuys Prognostic Index for the disease.

The patients were classified into two groups based on the margin of disease-free tissue surrounding the excised tumor. For patients with margins measuring less than 1mm, tumor removal was considered incomplete, and they were advised to undergo a repeat procedure. Of these patients, 124 refused an additional surgery and were considered as under treated DCIS patients for the purpose of this study. The 596 women with cancer-free margins equal to or greater than 1mm were deemed to be adequately treated. Groups also were broken down by severity of the disease. Kaplan-Mayer analysis determined local recurrence-free survival. Differences in outcomes were analyzed using the log-rank test.

Patients with low-grade DCIS and inadequate disease-free margins had an 18% probability of recurrence at five years and 53% at 10 years post-diagnosis. High-grade DCIS patients with inadequate treatment had probability rates of 55% and 67% recurrence respectively. By contrast, women with low-grade disease who were appropriately treated had significantly lower recurrence probabilities of 8% at five years and 13% at 10 years, while high grade disease recurrence was projected at 23% and 36%. Overall, mean tumor size was 17mm, and follow up was 79 months.

“This study clearly shows that excising DCIS with a minimum of 1mm margin of disease-free tissue is beneficial for many women and that further study is needed before current protocols are revised,” notes Dr. Khan. She notes that Dr. Silverstein, who is often regarded as a proponent of less aggressive DCIS treatment, always adheres to these margin guidelines. However, he has been a longtime critic of the overuse of routine radiation therapy for DCIS after adequate excision.”

“Women frequently come into our practice and say they have read that DCIS does not require treatment,” says Dr. Khan. “Clearly, our study suggests this is untrue. However, to some extent, the DCIS controversy has been distorted in the media and many women are confused.”

“The studies themselves are valid,” she says. “But much more research is needed before medical science, let alone the media, draws any hard and fast conclusions.”

Dr. Khan also feels that evaluating long-term overall quality of life in DCIS treatment should be given further emphasis. “Often preventing women from living with the aftermath of a subsequent treatment for invasive cancer is as important a goal as saving a life.”

**Abstract, Official Proceedings**

**Presenter:** Sadia Khan

**Institution:** Hoag Memorial Hospital Presbyterian

**Title:** Are We Over-Treating Ductal Carcinoma in Situ (DCIS)?

**Objective:** During early 2015, the media was flooded with the issue of whether or not ductal carcinoma in situ (DCIS) was being overtreated and whether favorable cases could be simply watched (core biopsy only, followed by surveillance). To help answer this question, we considered patients with DCIS treated with excision alone, with a final margin width less than 1 mm, as inadequately treated and a surrogate for no treatment (surveillance). We compared this group to patients with margin widths of 1 mm or more treated by excision alone.

**Methods:** We queried a prospective database for patients with DCIS treated with excision alone. Seven hundred twenty patients with pure DCIS (no invasion or microinvasion) were treated with excision alone and stratified into 2 groups based on margin width: 124 with margins less than 1 mm vs 596 with margins  $\geq 1$  mm. All patients with margins  $<1$  mm were advised to undergo re-excision but refused further treatment. Both groups were subdivided by grade. Nuclear grades I and II DCIS were statistically similar and grouped together as low-grade DCIS and compared to high grade (Grade III). Kaplan-Meier analysis was used to determine local recurrence-free survival. Differences in outcome were analyzed using the log-rank test.

**Results:** The results are tabulated below. The 5- and 10-year local recurrence probabilities are statistically significant ( $<0.001$ ) for low grade vs high grade and for narrow margins  $<1$  mm vs wide margins  $\geq 1$  mm. The comparison of excision alone with margins  $\geq 1$  mm for low-grade DCIS vs high-grade DCIS shows a 10-year local recurrence-free survival rate of 13% vs 36% ( $p < 0.001$ ). The patients who had margins of  $<1$  mm with no further treatment had higher rates of recurrence in both the low-grade group (55%) and high-grade group (67%) ( $p < 0.001$ ). These data show that leaving low-grade DCIS untreated would lead to local recurrence in more than half the patients over 5–10 years. Mean tumor size was 17 mm, mean age was 55 years, and mean follow-up was 79 months.

**Conclusion:** For patients with low-grade DCIS excised with margins  $\geq 1$  mm, excision alone results in local recurrence rates of 8 and 13% at 5 and 10 years. Local recurrence rates for patients with margins less than 1 mm are simply too high to consider this adequate treatment, regardless of grade. Core biopsy and surveillance alone for DCIS, regardless of grade is not adequate.

	DCIS Excision Alone Margin $<1$ mm		DCIS Excision Alone Margin $\geq 1$ mm	
	Grades I & II	Grade III	Grades I & II	Grade III

N	69	55	406	190
# Distant Recurrences	0	0	2	1
# Breast Cancer Deaths	0	0	1	0
5-Yr Probability Local Recurrence	18%	55%	8%	23%
10-Yr Probability Local Recurrence	53%	67%	13%	46%