



# Can we now reach a consensus on the management of benign papillary breast lesions?

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Management of benign breast lesions diagnosed by core needle biopsy (CNB) remains a controversial topic. Specifically, there is no consensus on the management of intraductal papillomas, despite multiple studies to determine whether excision or observation should be the next best step (1-5). When CNB yields a diagnosis of intraductal papilloma with atypia, excisional biopsy of the lesion is generally performed. For intraductal papillomas without atypia, however, a large retrospective study recently published in the *Annals of Surgical Oncology* suggests that observation without excision is likely a safe alternative (6). This is based on a low rate of malignancy found on surgical excision of 327 lesions diagnosed as benign papillomas on CNB, as well as no incidence of cancer found on follow-up for those (n=61) who did not undergo excision.

Like virtually all the studies on this subject, their study was retrospective, which is a weakness; however, the sample size is quite large. Because of the setting, a large integrated health care system, they were able to accumulate a large number of patients in a period of just 2 years. They focused on patients with benign papillary breast lesions presenting as a solid mass on imaging without any prior history of atypia or other high-risk lesions, prior breast cancer, or known genetic mutation. The exclusion of patients with prior history of breast cancer, similar to our study published last year, is important, because another recent study identified this as a risk factor for finding malignancy on excision of papillary lesions (3,7). Most of the patients (80%) in the Kaiser Permanente study underwent surgical excision, which is a minor weakness, since only a minority of their patients were observed without surgery. They

found a 9.5% rate of having a high-risk lesion on excision, which included atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ, and papilloma with atypia. Ductal carcinoma in situ (DCIS) was found in just 3.4% of excisions, while invasive cancer was found in 2.4%. This was quite similar to our finding of cancer (DCIS or invasive cancer) in only 7.5% of those who underwent excision after CNB of papillomas without atypia. Our study also compared this to patients with papillary lesions with atypia, for whom the upgrade rate to cancer was much higher (>30%). Along with this, we found that the proportion of patients with intraductal papilloma with atypia on CNB who had cancer on excision was similar to that for patients with intraductal papilloma and atypical ductal hyperplasia or atypical lobular hyperplasia. Kuehner *et al.* found the upgrade rate to be higher in those women with age greater than 50, a palpable breast mass, lesion size greater than one centimeter, or lesion location greater than 5 centimeters from the nipple. Upgrade was less common in those who presented with nipple discharge. Importantly, in the group of women diagnosed with invasive malignancy on excisional biopsy, the majority had low to intermediate grade, estrogen receptor positive, and node negative tumors. In the cohort of 61 women who did not undergo surgical excision, nearly 70% had follow up breast imaging within 13 months. They considered 2 years to be sufficient to rule out a cancer at the site of the papillary lesion. Whether this is long enough to rule out diagnosis of a slowly progressing malignancy is questionable, and they did not indicate the median follow-up for this group. In our series, 107 patients did not undergo excision after a CNB

with benign papilloma (which was equal to the number who did have excision), and the median follow-up period was >6 years. Four of the patients in the surveillance group eventually had a surgical excision, and one of those four had atypical ductal hyperplasia on final pathology. None were found to have a malignancy. The cancer-free survival for non-atypical papilloma patients, with or without surgical excision, was >90% at 10 years. The risk for patients with atypia was much higher, approximately 25–35% at 10 years. As pointed out by Kuehner *et al.*, high-risk lesions with atypia may be an indication for discussing more intensive screening or chemoprevention.

The findings reported in the Kaiser series are consistent with several other recent studies published on management of papillary lesions, which have found a malignancy risk in the range of 2–7% associated with benign papillary lesions (3,8,9). The rate of upstage is quite variable among published studies. As noted above, we found a striking difference between the risk of finding cancer with excision of intraductal papillomas with or without atypia (30% *vs.* 7.5%) (3). Similarly, Yu *et al.* reported an upgrade rate of 42% for those with atypia but only 4% for papillary lesions without atypia (10). A study published by Pareja *et al.*, looking at 196 excised intraductal papillomas, reported an upgrade rate of only 2.3% (11). All these studies point to similar conclusions: intraductal papillomas without atypia might have a different biology compared to those with atypia, as the risk of upgrade to malignancy is significantly different.

Overall what this new study and most of the recent literature published on benign papillary lesions suggest is that the decision for excision versus observation is not always easy. This should be a shared decision between the surgeon and patient, taking into account other risk factors and specific features of the lesion. The evidence shows significant variability in the risk of upgrade and the risk of malignancy, depending on patient factors, such as age, and tumor factors such as size and the presence or absence of atypia. Most importantly, the focus needs to be on the patient's comfort and anxiety, as there is no right answer for all patients with benign papillary lesions. Patients should be informed about the low risk of upgrade to cancer associated with benign papillary lesions without atypia, and we should allow them to be a part of the decision-making process in deciding whether to undergo excision versus observation.

In an era when we are debating whether even DCIS and small invasive cancers are being over-treated in some patients, it certainly seems appropriate to de-escalate the

treatment of papillary lesions of the breast, unless there are other significant risk factors. Thus, it is time for a consensus that patients with low-risk benign papillomas diagnosed by CNB and without significantly bothersome symptoms (e.g., copious nipple discharge or an anxiety provoking mass) can be safely followed. High-risk papillomas, particularly those with atypia, should generally be excised to rule out co-existing cancer, and these patients should continue to have close surveillance along with consideration of possible chemoprevention.

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