

# Benign Papilloma on Core Biopsy Requires Surgical Excision

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**Background:** When a papillary lesion is identified on core biopsy of an impalpable breast lesion, standard practice involves excisional biopsy. Recent literature has questioned the need for surgical excision in patients with benign core biopsy and radiological concordance. Our aim was to assess whether surgical excision is required by targeting this concordant group in a large screen-detected population.

**Methods:** A retrospective review of a prospectively collected database of all benign papillary core biopsies between February 1995 and September 2007 at North Western Breast Screen and Monash Breast Screen in Melbourne, Australia was performed. All patients had surgical excision, enabling correlation between core and final excisional biopsy results on all lesions. All histology reports were reviewed and the radiology was reassessed.

**Results:** During a 14-year period, 5783 core biopsies were performed from 633,163 screening mammograms. Eighty patients (0.01%) had benign papilloma on core biopsy, no patients had atypia on core biopsy, and all patients had benign radiological features. Of the 80 patients, 15 patients were found to have ductal carcinoma in situ (8) or invasive ductal carcinoma (7) on final pathology, yielding a 19% malignant rate.

**Conclusion:** Core biopsy showing benign papillary lesion, even where radiology is also suggestive of a benign process, cannot exclude malignancy, and therefore surgical excision is required.

**Key Words:** Papilloma—Biopsy—Needle—Mammography—Screening—Surgery.

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Population-based mammographic screening allows early diagnosis of many invasive and pre-invasive breast cancers, reducing the morbidity and mortality of the diseases.<sup>1,2</sup> Core biopsy of suspicious lesions provides preoperative histological diagnoses which facilitate appropriate surgical and systemic treatment.

Screening does however raise several management issues, among which is the appropriate management of various benign lesions that may be associated with an incidence of synchronous malignancy.

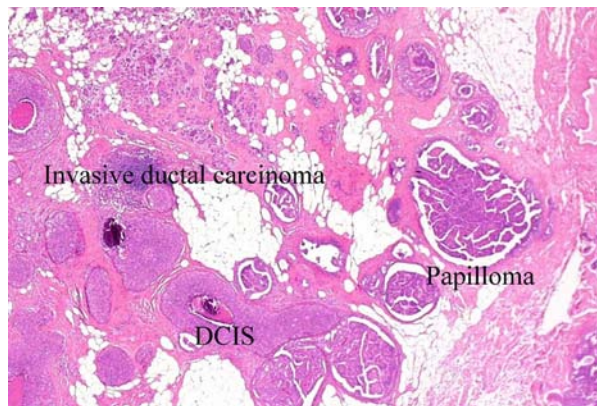
Papillary lesions of the breast account for 1–2% of breast neoplasia, <10% of benign breast tumours<sup>3,4</sup> and 0.16% of core biopsies.<sup>5</sup> Typically, papillary lesions are composed of branching papillae with a fibrovascular stalk covered by epithelial and myoepithelial cells.<sup>4</sup> The two main types of papillary lesions are the benign intraduct papilloma and papillary carcinoma in situ but the spectrum includes

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Published online May 13, 2008.

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**FIG. 1.** Histopathology of a benign papilloma with adjacent invasive ductal carcinoma and adjacent DCIS.

papillomatosis and papillomas with atypical ductal hyperplasia (ADH)<sup>6</sup> (Fig. 1). Generally, benign lesions are characterized by a uniform layer of myoepithelial cells, the loss of which heralds a malignant process.<sup>7</sup>

Large duct papillomas usually present with unilateral serous or blood-stained discharge, are rarely more than 1 cm in size and, when solitary, are considered benign and not a precursor for ductal carcinoma in situ (DCIS) or invasive cancer. Small duct papillomas are often deep in the breast and are usually asymptomatic; there is an increased incidence of breast cancer in patients with multiple papillomas.<sup>8-11</sup> Papillary carcinoma is defined by its papillary proliferations, with atypical epithelial cells exhibiting cellular monotony and the absence of myoepithelial cells.<sup>4</sup> Radiological features of papillary lesions are variable and include a mass, microcalcifications or a nonspecific density. There are no distinguishing features of a papillary lesion on either mammogram or ultrasound images. Features may suggest a benign or malignant process but benign radiology does not exclude a malignant lesion.

The standard practice in the management of papillary lesions has been surgical excision, on the premise that core biopsy may provide inadequate sampling of papillary lesions with subsequent false-negative diagnoses. At the commencement of our study, there were few studies addressing this issue and, as papillary lesions are relatively rare, studies had low sample sizes. Recent literature challenged this management, suggesting that concordance between core biopsy and radiological findings can obviate the need for surgical excision<sup>12-15</sup> in benign papillomas. Our study focuses on patients from the breast-screen population who had a benign papillary lesion on core biopsy with concordant radiology. Our primary aim was to assess the incidence of malig-

nancy discovered on the final histopathology from patients with benign core biopsies.

## METHODS

### Inclusion and Exclusion Criteria for Patient Selection

A prospective database has been maintained for all breast screen patients. From May 1995 until September, 2007, all patients who had papillary lesions on core biopsy in the breast-screen population were retrieved from the North-West and Monash Breast Screen services in Melbourne, Australia. Ethics approval was obtained from Breast Screen Victoria Research and Evaluation Committee. All core biopsies with benign papillary lesions were identified. Any lesion with atypical duct hyperplasia, DCIS or invasive carcinoma on core biopsy was excluded. All cases where a preoperative diagnosis was made on fine-needle aspiration cytology were excluded. Any patient with a suspicious radiological finding which would mandate surgical excision was also excluded. Hence, only those lesions with benign and concordant pathology and histology were included. All patients proceeded to surgical excision, enabling direct correlation between histological results.

### Percutaneous Biopsy Method

All biopsies were performed under stereotactic (800T, GE, Medical Systems<sup>®</sup>, or Nova, Mammomat 1000, Siemens<sup>®</sup>, Lorad DSM, Hologic) or ultrasonographic guidance (Antares Sonoline, Siemens<sup>®</sup>, or HDI 3000, ATL<sup>®</sup>). A median number of 4 (1-13) core biopsies were performed using a 14-gauge automated needle (ProMag Automatic, MD technologies<sup>®</sup> or Bard Magnum Biopsy<sup>®</sup>, Bard Limited<sup>®</sup> or Achieve, Programmable automatic biopsy system, Cardinal Health). Post-fire images of target lesions were performed and specimen X-rays for stereotactic biopsies were performed. All mammograms were reviewed independently by a single radiologist to ensure exclusion of suspicious radiology.

### Pathological Evaluation

Each core biopsy was fixed in neutral buffered formalin, embedded in paraffin wax and stained with haematoxylin and eosin using standard protocols. All papillary lesions with the characteristic fibrovascular core were included. Any lesion with significant cellular atypia was excluded. Excisional biopsy specimens were processed in a similar manner.

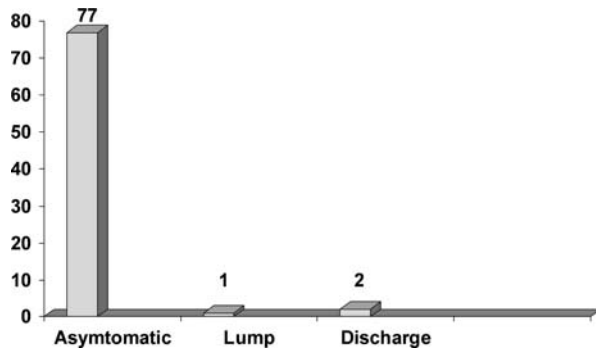


FIG. 2. Clinical presentation of the benign papillary lesions on core biopsy.

## RESULTS

During a 14.5-year period 633,331 screening mammograms and 5783 core biopsies were performed. Eighty patients (0.01%) had a benign papilloma on core biopsy. All patients had surgical excision. Median age was 61 (41–88) years. The majority of patients were asymptomatic (77) whilst one patient presented with a lump and two patients with discharge (Fig. 2). The majority of presentations were mass on mammography or ultrasound, with microcalcifications and non-specific densities less common (Fig. 3). The median core biopsy gauge was 14. Of the 80 patients who had benign core biopsies, 15 had malignant lesions on final histology (Table 1). Twenty-six patients were upgraded in the final pathology to atypical ductal hyperplasia (ADH) (11), ductal carcinoma in situ (DCIS) (8), invasive ductal carcinoma (IDC) (6) or invasive lobular carcinoma (1) (Table 2). As is shown in Table 1, the majority of the malignant lesions were found immediately adjacent to the papilloma. Fifty-four patients had concordant benign core and excisional biopsy histology but four of these had fibrocytic change only on final histology.

Of the patients excluded from the study, 33 patients were excluded due to atypical pathology and 3 patients had suspicious radiology on review. Four patients were excluded from the study as they elected for conservative follow-up. None of these patients developed malignancy with clinical follow-up and yearly mammograms.

## DISCUSSION

This is the largest study of benign papillomas, and highlights the need for surgical excision of all screen-detected “papillomas”. Even in cases with nonsuspicious

radiological findings, 14-gauge core biopsy is unable to reliably exclude malignant papillary lesions as benign and malignant components may coexist in the same lesion. Only 68% of benign cores had concordant final histology. Malignant invasive ductal or malignant papillary lesions were present in 19% and atypical lesions in a further 13%. Indeed there are no distinguishing radiological features of a papillary lesion, and histology is necessary for the diagnosis. As the accuracy of core biopsy in the assessment of papillary lesions has been variable, the universal practice regarding papillary lesions is inconsistent. A summary of the findings and conclusions of recent studies is presented in Table 3.

Surgical excision is the gold standard for papillary lesions. Recent papers have challenged this standard by suggesting that benign papillary lesions can be managed with clinical follow-up alone.<sup>13,15</sup> To assess our upgrade rate accurately, we excluded any patient that did not have a surgical excision (four patients due to patient wishes). Ivan et al. postulated that, provided benign papillomas had concordant imaging findings, they could avoid excisional biopsy.<sup>15</sup> Of 30 benign papillary lesions, none had subsequent malignant features. However, only 6 cases had surgical excision and the follow-up period ranged from 1 to 51 months. The nature of the follow-up, be it clinical or mammographic, was not specified and recommendations regarding frequency of follow-up were not provided. In the same year, Agoff<sup>13</sup> similarly advocated follow-up for benign core biopsies. Their mean length of follow-up was 35.6 months; the authors acknowledged the lack of long-term follow-up. These studies have been supported by others who have challenged the rate of malignancy, stating that these are the fault of sampling errors in clear cases of nonconcordant radiology.<sup>14,16</sup> We addressed these issues by re-evaluating all radiology, ensuring that suspicious lesions were excluded.

Recent reviews<sup>17</sup> and small reports have supported the need for surgical excision. Many studies are difficult to assess as they report all papillary lesions, including those with atypia, and the rate of surgical excision is variable. Table 2 provides a comparison between studies of benign papillary core biopsies. Liberman et al. and Mercado et al. have been particularly active in demonstrating the high malignancy rates in papillary lesions.<sup>3,7,18,19</sup> Liberman et al.<sup>18</sup> targeted concordant core biopsies and radiology in their recent series of 50 cases; only 50% proceeded to surgical excision. Although a short period of 2 years of mammographic follow-up was used to survey those who did not have surgical excision, 14% were

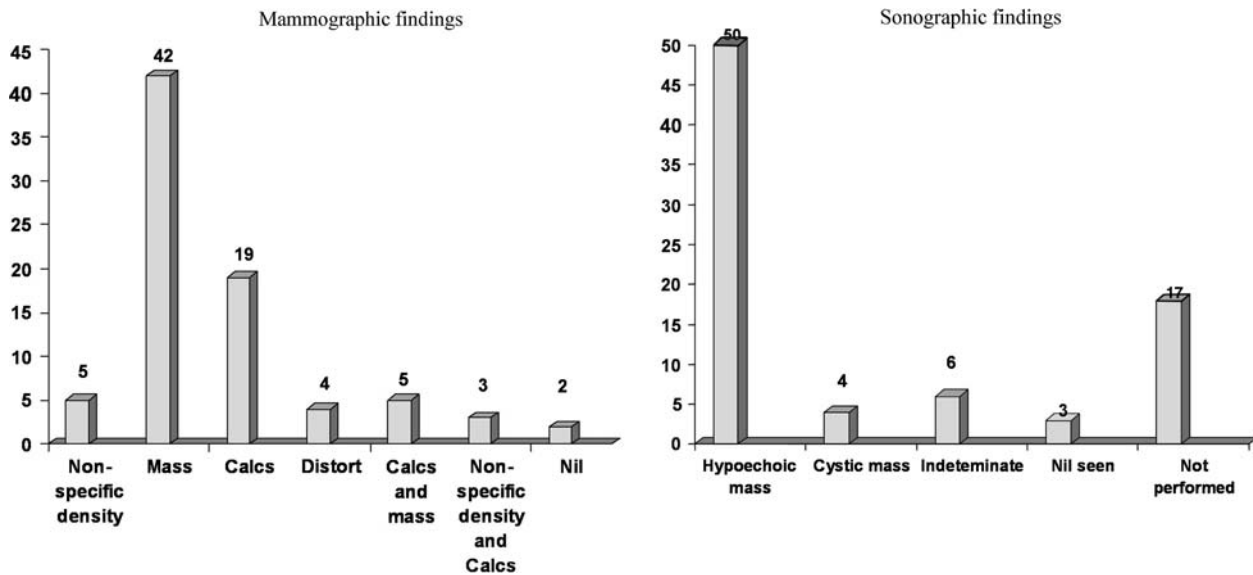


FIG. 3. Radiological features of benign papillary lesions on core biopsy. Calcs, calcifications; distort, architectural distortion.

TABLE 1. Malignant lesions on excisional biopsy

Patient	Age (years)	Biopsy histopathology	Mammographic findings	Ultrasonographic findings	Core biopsy gauge	Final histopathology
1	61	Ductal papilloma	Mass	Hypoechoic mass	14	G2 IDC
2	60	Intraductal papilloma	Nonspecific density and ca + +	Nil	9	Papilloma and papillary DCIS
3	76	Papilloma	Microcalcifications	Nil	11	Papilloma and papillary DCIS
4	63	Duct papilloma	Mass	Hypoechoic mass	14	Papilloma and papillary in situ carcinoma
5	88	Papillary lesion	Mass	Hypoechoic mass	14	Papilloma, ductal hyperplasia, LG cribriform DCIS
6	52	Intraductal papilloma	Mass	Hypoechoic mass	14	Papilloma and intracystic papillary carcinoma
7	76	Papillary lesion	Nonspecific density	Hypoechoic mass	14	Papillary DCIS
8	75	Sclerosing papilloma	Mass	Hypoechoic mass	14	Infiltrating papillary carcinoma
9	59	Intraductal papilloma	ca + +	Hypoechoic mass	11	Low grade papillary DCIS and IDC
10	54	Intraductal papilloma	Mass	Hypoechoic mass	14	Papilloma and Invasive lobular cancer
11	43	Intraductal papilloma	Microcalcifications	Hypoechoic mass	14	Papillary DCIS
12	64	Papillary epithelial hyperplasia	Mass	Hypoechoic mass	14	Papilloma and Solid intraduct papillary adenocarcinoma and DCIS
13	76	Papilloma	Mass, ca + +	Hypoechoic mass	14	Papilloma and solid papillary carcinoma
14	63	Benign duct papilloma	Mass	Hypoechoic mass	14	Benign intraduct papilloma and Invasive solid papillary carcinoma
15	79	Ductal papilloma	Mass	Hypoechoic mass	14	Papilloma and 15 mm intraductal papillary carcinoma

ca, calcifications.

TABLE 2. Final pathology found in cases of benign papilloma on core biopsy

Benign core	Benign excision	ADH	DCIS	Invasive cancer
80	54 (66%)	11 (12.7%)	8 (10%)	7 (8.8%)

found to have subsequent malignancy (one IDC and four DCIS), and 17% had high-risk lesions. Four of the cancers were found on interval follow-up due to

interval growth on mammography, new discharge or development of mass at the biopsy site. Additionally they looked at associated risk factors for malignancy and found family history and multiple papillomatosis to be clear, albeit expected, associations. Mercado et al. had similar findings in the benign concordant group with a high risk of upgrade to ADH or DCIS.<sup>19</sup> However, it is unclear whether papillomas with atypia were included. Arora et al.<sup>20,21</sup> have

**TABLE 3.** Benign papillomas diagnosed on core biopsy: summary of current literature

Study	Year	No. of cases	No. of excisions	Benign	Histopathology				Conclusions
					ADH	DCIS	Invasive	Other	
Our study	2007	80	80	54	11	8	7		Excise
Arora <sup>20</sup>	2007	18	18	18					Excise
Sydnor <sup>21</sup>	2007	38	38	37			1		No excision
Askenazi <sup>22</sup>	2007	39	20	13	3		4		Excise
Lieberman <sup>18</sup>	2006	50	25	20		4	1		Excise
Mercado <sup>19</sup>	2006	43	36	14	8	2		12 <sup>††</sup>	Excise
Valdes <sup>29</sup>	2006	36 <sup>#</sup>	36	30			6		Excise
Plantade <sup>30</sup>	2006	86	37	32		5			No excision
Carder <sup>12</sup>	2005	2	1	1					No excision
Agoff <sup>13</sup>	2004	25	11	11					No excision
Renshaw <sup>14</sup>	2004	8	8	8					No excision
Gendler <sup>8</sup>	2004	13	13	9	2		2		Excise
Rosen <sup>16</sup>	2002	44	14	11	2	1			No excision
Ivan <sup>15</sup>	2003	30	6	6					No excision
Puglisi <sup>31</sup>	2003	31	31	29			2		Excise
Irfan <sup>32</sup>	2002	6	3	1	1			1*	Inconclusive <sup>##</sup>
Ioffe <sup>33</sup>	2000	28	8	8					No excision
Philpotts <sup>34</sup>	2000	16	6	4				2*	No excision
Mercado <sup>7</sup>	2001	12	6	5			1 <sup>†</sup>		Excise
Lieberman <sup>3</sup>	2000	7	4	4					No excision

Only clearly benign papillomas are presented. No patients who had clinical follow-up had subsequent malignancy. Conclusions are a summary recommendation from publication.

\* Radial scar.

† This patient had discordant imaging.

†† 10 lesions had no residual findings on histopathology, 2 had papillomatosis.

# A small number of these benign lesions were diagnosed on fine-needle aspiration.

## Benign group too small to draw conclusions.

shown that atypia in the core biopsy has a significant increased risk of malignancy (0.005). Similarly, Sydnor et al. reported high malignancy rates in their atypical group (67%) but only 3% of benign cores had malignancy in the excision specimen. They concluded that the low malignancy rate supports follow-up alone. In contrast, our study is the largest to date that has excluded atypical lesions, and it still has a malignancy rate of 19%. This is supported by Ashkenazi's data<sup>22</sup> (20% in the truly benign group) and clearly highlights the risk of abandoning surgical excision. In a recent review, Valdes et al. concluded that the subtlety in diagnosing atypical features on core biopsy mandates surgical excision.<sup>17</sup>

Reports suggest that large-gauge core biopsies may be more accurate in the assessment of benignity of papillary lesions.<sup>23</sup> Liberman reviewed this issue and found no statistical difference between 11- and 14-gauge core biopsies.<sup>18</sup> Jackman also demonstrated that size of core biopsy could not predict benignity.<sup>24</sup>

The most encouraging data supporting core biopsy alone in distinguishing benign and malignant papillary lesions comes from immunohistochemical studies which suggest that different cell surface markers can aid differentiation. Saddik and Lai suggested CD 44

could be used as a marker for benign papillary lesions.<sup>25</sup> Their small series of 21 used immunohistochemistry on the excision biopsy specimens with >70% staining in benign lesions versus <10% in 80% of malignant lesions. As with most immunohistochemistry, the equivocal group would remain an issue necessitating surgery. However, accuracy may be increased if performed on the core biopsy.<sup>26</sup> Recently, high-molecular-weight cytokeratins, especially CK5 and 6 have been studied.<sup>27</sup> Shah et al. added CK5 and 6 to calponin and p63 and investigated their effect on the accuracy of core biopsies. By having four individual pathologists, the overall accuracy increased from 84.5% to 92.8%. No invasive cancer was diagnosed as a benign papillary lesion using this technique, but in one case DCIS was missed.<sup>28</sup> These emerging techniques remain helpful, but must be used in conjunction with morphological assessment.

## CONCLUSION

Core biopsy does not allow reliable exclusion of malignant papillary lesions. By excluding atypical lesions and evaluating a pure population of benign papillary lesions on core biopsy and radiology, the

series of papillomas in this study is the largest to date and demonstrates a 19% malignancy rate on final surgical excision. Surgical excision of all screen-detected papillomas remains the gold standard.

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