Vacuum assisted biopsy for percutaneous treatment of fibro-epithelial breast lesions in non-elective cases: study of 111 cases

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**Purpose**

Vacuum assisted elective percutaneous excision of fibroadenomas was approved by the FDA in 2004 as an alternative to surgery. Several series have demonstrated that the technique is feasible, secure, cost-effective, and that clinical results are comparable to those of surgery in terms of completeness of excision (1-5). On the other hand, morbidity of percutaneous excision is low, with fewer complications and less scarring than surgical removal.

Despite the good results obtained with percutaneous excision of typical fibroadenomas, surgery is still an indication for removal of complex fibroadenomas confirmed at core-biopsy and growing known fibroadenomas, due to the probability of associated carcinoma that has been referred between 2.9% and 5% of cases in literature (6-7).

The concept of complex fibroadenoma comprises the presence of either epithelial or stromal change. Epithelial changes in fibroadenomas include histological confirmation of either sclerosing adenosis, apocrine metaplasia with papillary changes, cysts <3 mm, ductal hyperplasia (either typical or atypical), or lobular neoplasia (7-11). Stromal changes include hypercellularity, mitosis or stromal overgrowth (8, 12). The significance of these changes has not been well established so far. The presence of epithelial changes has been associated both to underestimation and potential malignant transformation, while stromal changes have been related to the diagnosis of phyllodes tumours.

Increase in size up to 2-3 cm has been described in the natural history of fibroadenomas (13, 14). Nevertheless, fibroadenomas growth is considered a clinical sign of potential malignant or phyllodes transformation, especially in women over 35 years of age.

Core-biopsy and fine needle aspiration cytology have demonstrated several limitations in the diagnostic confirmation of these lesions, and although their management is still under discussion, surgery is considered a reasonably option (15-17).

The purpose of this work is to analyse vacuum assisted biopsy as a new indication for percutaneous excision of fibroadenomas in the two situations referred, as non-elective cases.
Methods and Materials

We reviewed a series of 111 lesions treated in two different centres (Breast Diagnostic Unit, La Rioja Hospital -Logroño, Spain- and Woman's Imaging Unit Grupo Hospital de Madrid -Madrid, Spain- ) during a period of six years (from January 2004 to August 2010). All patients were woman between 21 and 61 years of age.

Eighty two lesions corresponded to complex fibroadenomas and 29 to growing fibroadenomas confirmed at percutaneous interventional procedures.

1. Complex fibroadenomas

In this group, patients ranged between 21 and 61 years of age (median of 41.5 years). All the lesions were identified on ultrasound and confirmed as complex fibroadenomas at core-biopsy under ultrasound guidance. Median size of the lesions was 16 mm (5-40 mm). Thirty six lesions were palpable (43.9%) and 46 non-palpable (56.1%). Breast Imaging Reporting and Data System® classification of the degree of suspicion was as follow:

- BI-RADS® 3 - 45 (54.9%).
- BI-RADS® 4A - 30 (36.6%).
- BI-RADS® 4B - 4 (4.8%).
- BI-RADS® 4C - 2 (2.4%).
- BI-RADS® 5 - 1 (1.2%).

The 82 lesions were confirmed as complex fibroadenomas at core-biopsy (12G needles. (Magnum, Bard Medical division). Median number of cores was 6 specimens (ranging between 4 and 12).

Histological results at core-biopsy were: 66 fibroadenomas with epithelial changes without atypia, 6 with atypia, 9 stromal changes suspicious of phyllodes tumour and 1 fibroadenoma containing foci of lobular carcinoma in situ.

2. Growing fibroadenomas
Patients ranged between 25 and 52 years old (median of 41.5 years). All the lesions were identified on ultrasound (18 palpable and 9 non-palpable) and had an initial confirmation of fibroadenoma either at core-biopsy (21 cases) or at fine-needle aspiration cytology (8 cases). At the moment of the initial diagnosis, 18 lesions were classified as BI-RADS® 3 (62%), and 11 as BI-RADS® 4A (38%).

Increase in size at follow-up ranged between 10% and 79% for a time period from 3 to 23 months. At the time of percutaneous excision, lesion size ranged between 11 and 26 mm (median of 19.5 mm).

In all cases excision was recommended for both diagnostic confirmation and treatment. Percutaneous removal was offered as an alternative to surgery with discussion of advantages and disadvantages with the patient and the referring physician. Informed consent was accomplished according to the protocols established in each centre.

**Percutaneous excision procedure**

Percutaneous excision was performed with two different vacuum assisted devices: 11G Mamotome (Mamotomo, Gynecare Endosurgery) in 77 cases (69%) and 10G Encor (Encor, SenoRx) in the remaining 34 cases (31%).

In all cases the goal was complete excision of the visible lesion (Video 1). Median time of the procedures was 45 minutes (ranging from 30 to 70 minutes) and the number of cores ranged between 5 and 206 samples. We had no complications that required surgical treatment.

Histological analysis included Haematoxylin-Eosin stains and immunohistochemical techniques when they were required by the pathologists.
Fig. 1: Video 1- Percutaneous excision of complex fibroadenoma

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Results

1. Complex fibroadenomas

Seventy six lesions were excised at the time of core-biopsy confirmation and 6 after follow-up, due to increase in size.

Complete excision was achieved in 64 cases (78%). Histological results are shown in table 1. Benign lesions (figures 1-2) were confirmed at vacuum assisted biopsy in 70 cases (85.4%), atypical ductal hyperplasia in 3 (3.7%), phyllodes tumour (figure 3) in 2 (2.4%) and carcinoma in 4 cases (4.8%). All carcinomas had an initial diagnosis at core-biopsy of either atypical hyperplasia (3 cases) or lobular carcinoma (figure 4) in situ (1 case).

Surgical excision was recommended after vacuum biopsy in 8 cases: 4 for treatment (1 ductal carcinoma in situ, 1 infiltrating ductal carcinoma with associated in situ ductal carcinoma and 2 confirmed phyllodes tumours) and 4 for diagnostic confirmation (1 ductal atypical hyperplasia BI-RADS® 5 and 3 suspicious of phyllodes tumours). All malignant cases and 4 phyllodes tumours were confirmed at surgery. The case of ductal atypical hyperplasia was confirmed as a complex lesion with atypia, without malignant cells.

In the remaining cases, those with benign pathology at vacuum biopsy were followed up, 2 cases of atypical hyperplasia were completely excised percutaneously and surgery was not indicated, 1 suspicious of phyllodes tumour rejected surgery and the two cases of fibroadenomas with associated lobular carcinoma in situ were completely excised at percutaneous vacuum biopsy and no risk lesions were found outside the fibroadenomas (no residual lesions were confirmed at initial imaging follow-up, and both patients were set on a high risk follow-up protocol).

Vacuum assisted biopsy avoided open surgical biopsy in 78 cases (95%).

2. Growing fibroadenomas

Complete percutaneous excision was achieved in 22 cases (76%).

Histological results are shown in table 2. Benignity was confirmed percutaneously in 26 cases (89.5%, 6 of them complex fibroadenomas with typical ductal hyperplasia), ductal atypical hyperplasia in 2 (7%) and fibroadenoma with lobular carcinoma in situ...
in 1 case (3.5%). Two cases not completely percutaneously removed, were sent to surgery: 1 complex fibroadenoma with typical ductal hyperplasia (confirmed as benign at surgery) and the fibroadenoma with lobular carcinoma in situ associated (infiltrating ductal carcinoma was confirmed at surgery).

Vacuum asisisted biopsy avoided open surgical biopsy in 27 cases (93%).

3. Total series

Complete excision was achieved in 77.5%, total incidence of carcinoma was 4.5% and surgical diagnostic biopsy was avoided in 105 cases (94.6%).
### Table 1 – Histological results in Complex Fibroadenomas

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CFA-EC – Complex Fibroadenoma with Epithelial Changes  
CFA-AH – Complex Fibroadenoma with Atypical Hyperplasia  
CFA-LCIS – Complex Fibroadenoma with Lobular Carcinoma in Situ  
S. PHYLLODES – Suspicious of Phyllodes Tumour  
CFA-DCIS - Complex Fibroadenoma with Ductal Carcinoma in Situ  
CFA-IDC - Complex Fibroadenoma with Infiltrating Ductal Carcinoma

**Fig. 0**

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Figure 1 – 40 year-old woman with a 17 mm palpable BI-RADS® 3 nodule (A). Histology of complex fibroadenoma (sclerosing adenosis and apocrine metaplasia) at core-biopsy (B). Vacuum assisted percutaneous excision (C) confirmed the same histology. No surgery was required.

Fig. 0

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Figure 2 – 38 year-old woman with a 13 mm non-palpable BI-RADS® 3 nodule (A). Histology of complex fibroadenoma with atypical hyperplasia at core-biopsy (B). Vacuum assisted percutaneous excision (C) confirmed fibroadenoma without atypia. No surgery was required.

Fig. 0

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Figure 3 – 44 year-old woman with a 14 mm palpable BI-RADS® 4A nodule (A). Histology of fibroadenoma with suspicion of Phyllodes tumour at core-biopsy due to stromal overgrowth and isolated mitosis (B). Vacuum assisted percutaneous excision (C) confirmed Phyllodes tumour. No residual lesion was identified at surgery.

Fig. 0

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Figure 4 – 41 year-old woman with an 8 mm non-palpable BI-RADS® 3 nodule (A). Histology of complex fibroadenoma with lobular carcinoma in situ at core-biopsy (B). Vacuum assisted percutaneous excision (C) confirmed the same diagnosis without evidence of risk lesions outside the nodule. No surgery was performed.

Fig. 0

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### TABLE 2 – Histological results in Growing Fibroadenomas

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**CORE-BIOPSY / FNA**

**FIBROADENOMA**

*CFA-EC* – Complex Fibroadenoma with Epithelial Changes  
*CFA-AH* – Complex Fibroadenoma with Atypical Hyperplasia  
*CFA-HD* – Complex Fibroadenoma with Ductal Hyperplasia  
*CFA-LCIS* – Complex Fibroadenoma with Lobular Carcinoma in Situ

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**Fig. 0**

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Conclusion

- In our series, the incidence of carcinoma was 4.5% (in the range of that described in literature), superior for complex (4.8%) compared to growing fibroadenomas (3.5%).

- In complex fibroadenomas, all malignant cases confirmed at vacuum biopsy, showed either ductal atypia or lobular neoplasia at core-biopsy. In growing fibroadenomas, the only malignant case was confirmed as vacuum underestimation of lobular carcinoma in situ with incomplete percutaneous excision.

- Complete excision was achieved in 77.5% of cases in the total series (slightly superior figures for complex -78%- versus growing -76%- fibroadenomas).

- Complete percutaneous excision of fibroadenomas with foci of lobular carcinoma in situ has been considered therapeutic as long as the neoplastic component was confined to the fibroadenoma and no risk lesions were found outside the lesion. These patients were considered as high risk population and are under follow-up at the moment.

- Vacuum assisted biopsy avoided open surgical biopsy in 94.6% of cases in the total series, with more favourable results for complex (95%) than for growing (93%) fibroadenomas.

- Our results show that vacuum assisted biopsy could be considered as an indication for percutaneous excision of fibroepithelial lesions in non-elective cases, and could be therapeutic in selected cases of fibroadenomas with lobular carcinoma in situ, although more research is needed to establish the security of the technique in this last situation.
References


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