The American Journal of Surgery (2014) 208, 260-267

The American Journal of Surgery®

Clinical Science

Management of patients diagnosed with atypical ductal hyperplasia by vacuum-assisted core biopsy: a prospective assessment of the guidelines used at our institution

Alizée Caplain, M.D.[a], Youenn Drouet, Ph.D.[b,c], Mathilde Peyron[d], Marie Peix, M.D.[e], Christelle Faure, M.D.[a], Catherine Chassagne-Clément, M.D.[d], Frédéric Beurrier, M.D.[a], Marie-Eve Fondrevelle, M.D.[d], Nicole Guérin, M.D.[e], Christine Lasset, M.D., Ph.D.[b,c], Isabelle Treilleux, M.D., Ph.D.[d,*]

[a]*Department of Oncologic Surgery,* [b]*Department of Public Health, Centre Léon Bérard, Lyon, France;* [c]*Université Lyon 1, CNRS UMR 5558;* [d]*Department of Pathology,* [e]*Department of Radiology, Centre Léon Bérard, Lyon, France*

KEYWORDS:
Atypical ductal hyperplasia;
Prospective study;
Directional vacuum-assisted biopsy;
Upstaging–underestimation;
Mammographic follow-up;
Surgical excision

Abstract

BACKGROUND: Because of underestimation, surgical excision is recommended for atypical ductal hyperplasia diagnosed on directional vacuum-assisted biopsies. The following guidelines have been established according to our retrospective study published in 2008: excision for lesions ≥21 mm, follow-up for lesions <6 mm with complete removal of microcalcifications, and follow-up or excision for 6 to 21-mm lesions with respectively less or >2 atypical ductal hyperplasia foci.

METHODS AND RESULTS: These guidelines were assessed in a prospective series of 124 patients with a median follow-up of 30 months. Conformity rate was 92%. Upgrading was 28% (15 of 53 patients) for conformed surgery and absent for surgery performed beyond the scope of guidelines. For the patients with benign result at surgery ($n = 38$) or just followed ($n = 61$), 3 cancers occurred in either breast at 1 to 3 years.

CONCLUSIONS: These convenient guidelines can safely spare surgery for a subset of patients. However, annual mammographic follow-up is recommended since the risk of subsequent cancer remains high for both breasts.

With the common use of breast core-needle biopsy (CNB) and the recent assessment of the directional vacuum-assisted biopsy (DVAB) technique,[1] up to 15% of breast biopsies performed for isolated mammographic calcifications highlight an atypical ductal hyperplasia (ADH) diagnosis. ADH is a proliferative lesion which is a marker of an increased risk of developing breast cancer and is histopathologically defined as either (1) an hyperplastic lesion with some cytological features of low-grade ductal carcinoma in situ (DCIS) that does not fill the entire duct; or (2) a lesion with classic cytological and architectural features of low-grade DCIS measuring <2 to 3 mm.[2–4] Patients with ADH on surgical breast biopsy are 4 to 5 times more at risk than the general population of subsequently developing breast cancer.[2] After diagnosis of ADH on CNB, a surgical excision is currently recommended

The authors declare no conflicts of interest.

* Corresponding author. Tel.: +33-(0)4-78-78-28-39; fax: +33-(0)4-78-78-27-13.
E-mail address: isabelle.treilleux@lyon.unicancer.fr

Manuscript received June 27, 2013; revised manuscript October 2, 2013

0002-9610/$ - see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.amjsurg.2013.10.029

because of the risk of upstaging to DCIS or invasive cancer on the definitive evaluation of the excised specimen.[5–14] Many studies focused on this underestimation rate, with a prevalence of upstaging ranging from 11% to 68% after CNB.[5,8,10,11,15–21] Some of them tried to highlight predictive factors of underestimation, but decision criteria whether to excise or not differ according to the authors[1,6,8,17,21–25] and none of them have been prospectively assessed. Up to now, no clear guidelines for the management of patients diagnosed with ADH on DVAB have been ascertained.

To identify a subset of patients who could safely be spared surgery, a previous retrospective study was conducted at our institution on a series of 300 patients diagnosed with pure ADH on 11-gauge DVAB between February 1999 and May 2005.[26] Valuable features were identified to classify patients at diagnosis based on the 3 following criteria: size of the lesion on mammograms, complete removal of microcalcifications by DVAB, and extent of ADH within ducts and/or lobules on CNB defined as "ADH foci."[17] This analysis led us to a proposal for the management of patients with ADH, shown in Fig. 1.

This study aims to prospectively assess the relevance of these guidelines which have been used at our institution for ADH management since June 2007.

Patients and Methods

ADH diagnosis and study database

From June 2007 to June 2012, 2,030 consecutive 10-gauge DVABs (Vacora or Sonorex: Bard, France) were performed at the Centre Léon Bérard as part of a breast cancer screening program, with 127 cases of pure ADH diagnosed. All DVABs were performed for mammographic microcalcifications by well-trained radiologists and were obtained with a prone-dedicated stereotactic device (Lorad Multicare Platinum, Hologic Inc, Danbury, CT). Only isolated microcalcifications were included since the underestimation rate could be higher on patients having either a palpable mass or another mammographic lesion.[18,27] Patients for whom ADH was associated with other histopathological borderline lesions (such as papilloma, radial scare, mucocele-like lesion, or atypical columnar cell metaplasia) were excluded from the study because they might increase underestimation.[14,19] Before biopsy, the mammogram findings classified according to the Breast Imaging-Reporting And Data System (BI-RADS)[28] were reviewed by the same radiologist. The size of each microcalcification cluster (lesion size in millimeter) was recorded. A metallic marker was left in the targeted area after the biopsy and both the right position of the marker and the complete or partial removal of calcifications were assessed. A radiography of the core samples was systematically performed to confirm the presence of microcalcifications. The diagnosis of ADH as the most aggressive lesion was made by 2 pathologists specialized in breast pathology, according to established criteria as defined by Page et al and Tavassoli and Norris.[2–4] The extent of ADH within ducts, as described by Ely et al,[17] was assessed by the same pathologists. Therapeutic decision was taken by a multidisciplinary team, according to the guidelines previously described. In case of surgical management, a preoperative needle localization and an intraoperative specimen radiography were performed to confirm correct excision. Pathological diagnoses on excision were classified as benign (ADH or other benign lesions) or malignant (DCIS, in situ pleomorphic lobular carcinoma, or invasive carcinoma). In all cases, the presence of a prior biopsy site was confirmed. Demographical data (age, side affected), lesion size on mammograms, number of cores removed, ADH extension within ducts (foci), complete removal of microcalcifications, final therapeutic decision, and definitive diagnosis on surgical specimen were prospectively entered in our database. Three patients with a lesion size missing were excluded from the analysis since the conformity to guidelines of the final therapeutic decision could not be evaluated without this criterion. The following analysis was thus carried out on a series of 124 patients with assessable conformity to guidelines. Patients have given their informed consent, and approval was obtained from the review board of the Centre Léon Bérard.

Follow-up

Outcome and follow-up after ADH diagnosis, including clinical, mammographic, and histopathological data when a

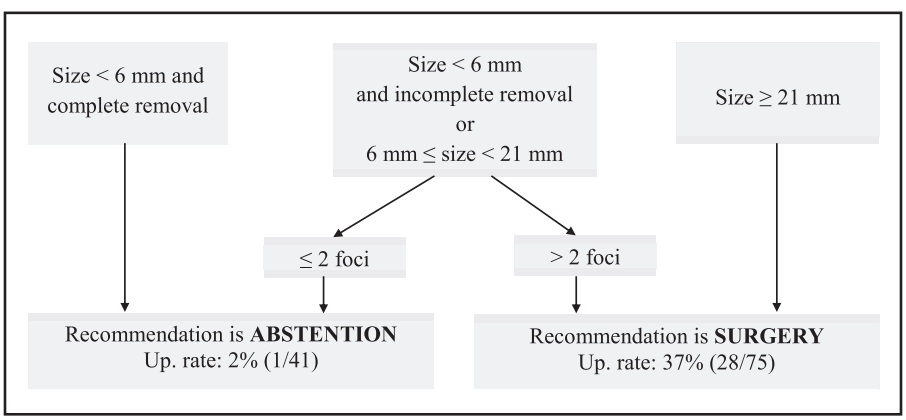

Figure 1 Actual guidelines. (Forgeard et al[26])