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Breast ductoscopy with a 0.55-mm mini-endoscope for direct visualization of intraductal lesions

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New instrumentation

Abstract. Standard radiologic examinations of breast duct lesions can give only indirect information. Mini-endoscopy with a breast ductoscope of only 0.55 mm offers direct visualization of the lesion and helps in the decision to perform or avoid exploratory breast tissue resection. We used a LaDuScope (PolyDiagnost, Pfaffenhofen, Germany) with a 0.55- or 0.95-mm outer diameter and a 75-mm working length from October 2003 through July 2004 on 11 women (average age of 48.3 years [range 36–69 years]) with suspicious nipple discharge. The optics have zero-degree direct view, 70-degree field vision, and 3000 or 6000 pixel resolution. Breast ducts and walls could be easily inspected; and irrigation of breast ducts, aspiration, and use of cytology brush were possible under visual control. We had no intraoperative or postoperative complications. The new procedure of mini-ductoscopy is feasible, safe, and helpful as an additional ambulatory diagnostic method for visual inspection of breast ducts. This instrument demonstrates the latest advances of technology and a trend toward less-invasive diagnostics for breast duct lesions.

For several years, there has been a continuing trend for less-invasive breast surgery. Breast-conserving surgery has become the standard of care for small tumors in the breast.[1,2] Although endoscopic operative techniques previously have been used for breast surgery and axillary lymph node dissection,[3] in breast diagnostics, physicians mainly have to rely on indirect visualization techniques like mammography, breast magnetic resonance imaging, or galactography. These standard diagnostic modalities are used to evaluate suspicious or bloody nipple discharge, but they can give only indirect information about the source of bleeding that is suspected of coming from a breast duct lesion.

Bloody nipple discharge (Figure 1) often is benign but sometimes has a malignant cause. When palpation, breast ultrasound, mammography, laboratory hormone results, and bacterial culture and cytologic results are inconclusive, mini-endoscopy can be performed for acquiring additional direct visual information from inside the breast duct, which might delay or possibly even prevent potential exploratory operative breast tissue biopsy.

Mini-endoscopy with a new type of breast ductoscope with an outer diameter of only 0.55 mm can offer visualization of intraductal breast lesions. We evaluated mini-ductoscopy with this new type of miniaturized ductoscope and its performance in our institution in a first series of 11 patients.

Materials and methods

Ductoscopes

We used small- and medium-size ductoscopes: LaDuScope S and LaDuScope M, with a 0.55-mm and 0.95-mm outer

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Figure 1 Provoked bloody nipple discharge of the left breast.

diameter metal cannula, respectively, (Figure 2) manufactured by PolyDiagnost GmbH (Pfaffenhofen, Germany). All equipment for ductoscopy is commercially available and certified as medical devices with CE mark for Europe; FDA approval in the United States is pending.

Although the cannula is made of metal, due to its small diameter it tolerates some bending and has some flexibility without breaking. The smaller optic has an outer diameter of 0.36 mm and 3000 pixel resolution, the medium-size optic has an outer diameter of 0.77 mm and 6000 pixel resolution. Both ductoscopes have a working length of 75 mm, a total length of 120 mm, with a zero degree–angle direct view and a field of vision of 70 degrees. They both have a Luer lock attached on the side to allow irrigation as well as aspiration of the breast ducts with a syringe under visual control. The scopes are autoclavable and can also be sterilized with gas or plasma. The ductoscope is connected with a thin, flexible fiber optic cable to the ocular that is attached analog to endoscopic/laparoscopic equipment with a standard endoscopic camera system. The cost for a single ductoscope is approximately $7500.00. Additional features are available:

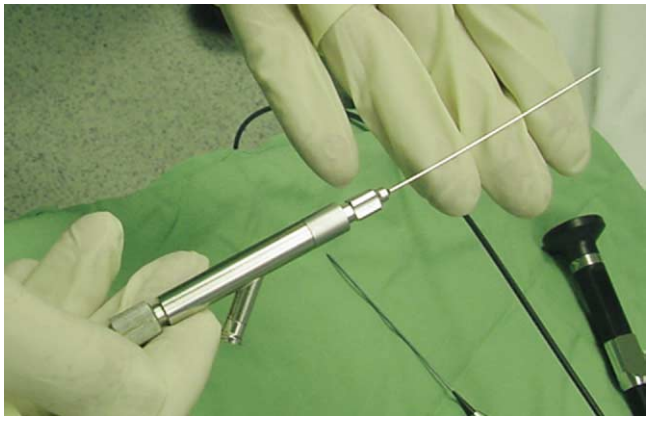

Figure 2 The thin cannula of a 0.95-mm LaDuScope M breast ductoscope.

Figure 3 Dilatation and sounding with a 0.7-mm Baumann probe of the left retromamillary breast sphincter as preparation for introduction of the ductoscope.

a Baumann dilator probe (Figure 3) with a 0.7-, 0.8-, 0.9-, or 1.1-mm diameter, a reusable cytology brush with a 0.38-mm diameter with introduction adapter for taking cytology specimens of suspicious lesions under visual control, and a grasping basket of 0.38 mm for removal of intraductal specimens (e.g., papillomas). Same-size grasping forceps and laser fiber for use through a working channel will be available soon.

Operating room

Although not a definite requirement, our first series of 11 ductoscopies was performed in the operating room under usual sterile conditions (Figure 4). Eventually, we expect to be able to perform it as an ambulatory diagnostic procedure in the outpatient clinic. The operating room setting includes a sterile table and an endoscopy camera unit with a monitor, which is placed so that physician, assistant, and patient can visualize the procedure. Results of the ductoscopy can be explained immediately to the patient, and the entire procedure also is recorded on a CD-Rom (VDR-3000, Datavideo Technologies, Taipeh, Taiwan) for later reevaluation, a second opinion, or teaching purposes.

Performance of ductoscopy

Until ductoscopy is established as a routine procedure in our department, potential patients with nipple discharge who might benefit from using this technique are asked preoperatively for informed consent, so far on an experi-