

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

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KEYWORDS:

Ductoscopy;
Mini-endoscopy;
Nipple discharge;
Intraductal lesion;
Breast cancer;
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.

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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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Submitted October 12, 2004. Accepted for publication February 28, 2005.



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:

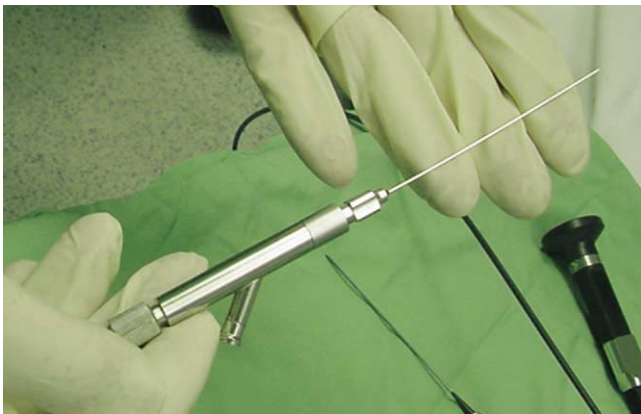


Figure 2 The thin cannula of a 0.95-mm LaDuScope M breast ductoscope.



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, Taipei, 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-

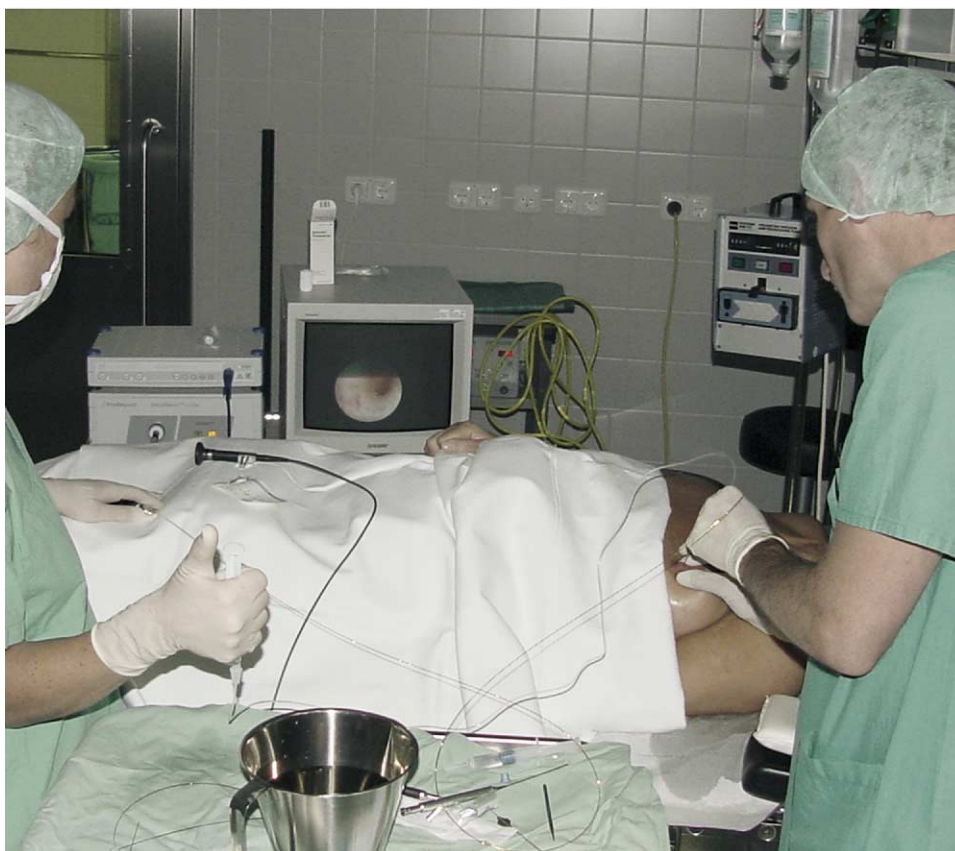


Figure 4 Operation room setting for breast ductoscopy.

mental basis. Mini-ductoscopy can be performed either as an ambulatory diagnostic procedure or as an intraoperative diagnostic modality.

The patient is placed on a flat table, the breast and the nipple area are locally disinfected, and the surrounding skin is covered with sterile sheets. Locally applied sterile anesthesia spray or gel (e.g., mepivacaine 5–10 mg/mL [Scandicain; AstraZeneca, Wedel, Germany] or lidocaine 25 mg and prilocaine 25 mg [EMLA, AstraZeneca]) desensitizes the nipple area and allows manipulation for dilatation of the retromamillary sphincter and introduction of the ductoscope. Dilatation of the sphincter and introduction of the ductoscope is the most difficult part of the procedure: because of twisting and kinked breast ducts, the dilatation probe or ductoscope can easily be placed extraductal into mammary tissue. This is usually noticed through visualization of yellow intramammary fat tissue. If this occurs, the device, because of its thin diameter, is mainly displacing breast tissue—we never saw bleeding—and it can be withdrawn without further action. However, misplacement should be avoided because it can worsen or even make the intraluminal introduction of an instrument impossible. When introduction into the breast duct is not easy, we use an operating room microscope.

Normal breast duct walls with duct bifurcation are shown in [Figure 5](#), with intraductal mucous in [Figure 6](#). Movement inside the breast tissue is easy and does not cause any

discomfort to the patient. In contrast to standard endoscopic procedures, instead of moving the scope, the breast tissue is pushed toward the region of interest. The patient usually is awake for ductoscopy; a slight dose of sedation (e.g., 2–5 mg diazepam) eases tension and discomfort during dilatation of the mamillary duct, which seems to be the only uncomfortable moment for the patient during the entire procedure.

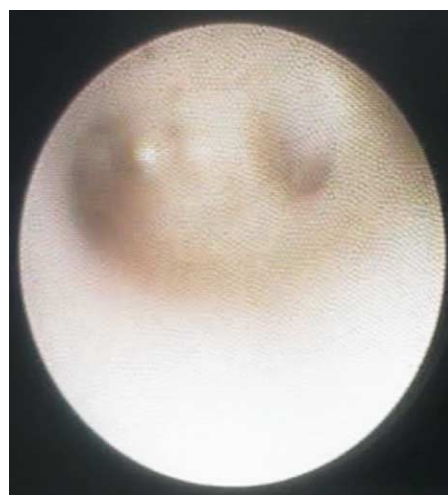


Figure 5 Breast duct bifurcation.



Figure 6 Breast duct with mucous.

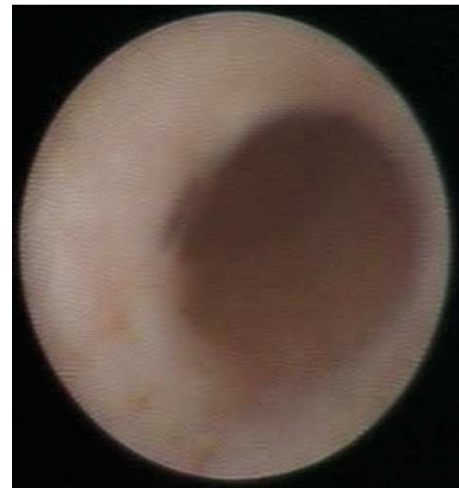


Figure 7 Reddish duct wall spots in a patient with ductal carcinoma in situ.

Although for all ductoscopies performed so far we had anesthesia stand-by in the operating room as a precaution, we expect in the future to be able to do without it. The results are explained to the patient either during the procedure or postoperatively, as well as if the procedure was sufficient or if further measures, such as breast ultrasound or a follow-up visit, are recommended.

Results

From October 2003 through July 2004, 11 ductoscopies were performed for one-sided suspicious and/or bloody nipple discharge (Figure 1) with a mean follow-up time of 4.49 months (range, 0–9 months). The average age was 48.3 years (range, 36–69 years), and the distribution regarding breast side was almost even with six right and five left breasts. After introduction of the ductoscope, in most cases the breast ducts and walls could be inspected easily. We had no intraoperative or postoperative complications. In three patients, we had an uneventful introduction of the device into mammary tissue; in one patient, ductoscopy failed after previous intramammary placement.

In nine patients, we did not visualize during ductoscopy any obvious intraductal lesions or signs of malignancy. In one patient, we noticed some reddish spots on the duct wall (Figure 7), and the histologic report confirmed ductal carcinoma in situ (DCIS). In 8 (72.7%) of 11 patients, cytology was performed preoperatively or under visual control with the cytology brush during ductoscopy (Figure 8). Also in eight patients, breast tissue and/or breast ducts were operatively removed after ductoscopy. A correlation of cytology and histology results (Table 1) showed that in four (80%) of five patients in whom cytology and histology were performed, the result of both was conclusive. Only the patient with DCIS had normal breast cytology (patient #9, Table 1). Due to limited experience and being early in the learning curve, the intraductal lesion in patient #6 was not seen; and

in patient #9, the reddish duct walls were identified as not normal during ductoscopy but a visual diagnosis could not be made at that time because we had never seen an intraductal picture of DCIS before.

Discussion

Development of ductoscopy

Although ductoscopy was introduced as a concept in 1988⁴ and evaluated in the late 1980s and early 1990s,^{5–7} it has recently spawned interest worldwide, especially in Japan,^{8–13} the United States,^{14–17} Europe,^{18–24} and even China.^{25,26} With new innovation of technology and improvement of manufacturing processes resulting in further miniaturization in size and improvement of optical resolution, mini-ductoscopes were developed with a 0.55-mm outer diameter.

Evaluation of technique

In our experience to date, the ductoscopy technique is feasible and safe and can serve as an additional ambulatory or intraoperative modality for suspicious nipple discharge.



Figure 8 Intraductal brush cytology (upper right).

Table 1 Correlation of cytology and histology results for patients who had breast ductoscopy

Patient	Cytology	Histology
#1	Not done	Not done
#2	Normal	Not done
#3	Suspicious	Intraductal papilloma
#4	Not done	Normal
#5	Not done	Nonspecific chronic inflammation
#6	Normal	Fibroadenoma
#7	Technical failure*	Fibroadenoma
#8	Normal	Normal
#9	Normal	Ductal carcinoma in situ pTis (m)
#10	Technical failure*	Not done
#11	Suspicious	Metaplasia

*Repetition recommended by pathologist.

The physician is able to directly visualize the breast duct and potential intraductal lesions, for which only indirect methods were available previously. The most difficult part is the dilatation of the retromamillary sphincter and the introduction of dilator probe and ductoscope because extraductal placement of the probe and ductoscope can occur easily. However, if it occurs, intramammary yellow fat tissue can be seen and confirms the incorrect placement; but due to the very small diameter of the ductoscope, no bleeding results, and the scope or probe can be withdrawn without further measures. Use of an operating room microscope for identification and localization of the entrance has improved the introduction of dilator probe and ductoscope for difficult cases. In our study, the distribution of histologic results was similar to others published.^{25,27}

Learning curve

The learning curve for ductoscopy in our experience consists of two things: safe and reliable performance of ductoscopy and accurate identification of intraductal lesions. Knowledge of the three-dimensional breast duct anatomy²⁸ is necessary. To avoid loss of orientation in a multiduct system with limited spatial orientation, it would be helpful to have a marker technique (e.g., metal clips or [semi] permanent colors) to mark ducts either to avoid ducts already inspected or for recovery of previously seen suspicious intraductal lesions. For accurate visual identification of lesions, long-term experience seems to be necessary, and an atlas of normal and pathologic findings would also be helpful. Attempts for a classification of intraductal lesions have already been made.⁸

Ductal lavage and breast duct cytology

The role of ductal lavage^{16,29,30} and breast duct cytology³¹ as well as the predictive value of the combination of ductal lavage, cytology, and ductoscopy have to be determined in future studies. New instruments like the intraduc-

tal micro grasper or basket have to be evaluated and might move ductoscopy forward to an independent procedure with the potential to substitute and eliminate otherwise necessary breast biopsies following the trend toward a less-invasive breast diagnostics and surgery.³² The only limitation of this technique so far is that the picture on the monitor, due to the limited resolution of 3000 and 6000 pixels, is rather small compared with standard full size-screen endoscopy pictures.

Reimbursement for ductoscopy by health insurance in Germany

Due to the fact that ductoscopy is a new type of procedure, it can't be coded at the present time within the German OPS-301 procedure classification system. However, our university clinic has a special agreement with health insurance companies to pay a flat-fee, all-inclusive price of approximately \$330.00 per ductoscopy (including physician's service) for patients with basic health insurance and privately insured patients. This does not cover our costs, but permits a university clinic the opportunity to develop new techniques.

Perspective and tasks for the future

Comprehensive evaluation of ductoscopy, like the multinational MEND-Trial for systematic evaluation of nipple discharge initiated by Beechey-Newman et al of Guy's Hospital in London, UK, is the first step to objectively verify sensitivity and specificity of ductoscopy. Establishing training courses and sharing experience with interested colleagues are necessary to reach critical mass and move forward with this new diagnostic technique. The introduction of therapeutic instruments like grasper, basket, or laser fiber might even allow intraductal therapeutic options. The foundation of an International Society of Mammary Endoscopy (ISOME; www.isome.org) is in progress.

Conclusion

Mini-ductoscopy is feasible and safe and can be helpful as an additional ambulatory diagnostic method to exclude obvious causes for nipple discharge. Further studies and development of this technique and its diagnostic and therapeutic options are necessary. This instrument demonstrates the latest advances of technology and supports the trend toward less-invasive diagnostic methods for examining breast ducts.

Note: This manuscript raised considerable debate among the reviewers and editors as to whether The Journal of Minimally Invasive Gynecology was the proper venue for publication because gynecologists usually are not involved in breast surgery. On the other hand, gynecologists,

initially, probably diagnose breast disease more than any other group of physicians. Additionally, this is certainly an endoscopic technique that may pique the interest of some of our readers.

Editor

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