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A randomized controlled study of selective microdochectomy guided by ductoscopic wire marking or methylene blue injection

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Abstract

BACKGROUND: Methylene blue identification of lesions during microdochectomy is often inaccurate, resulting in large dissection and tissue damage. A wire placed via ductoscopy preoperatively into the pathologic duct may aid identification and reduce the amount of dissection required.

METHODS: A total of 53 patients being evaluated for nipple discharge were randomized to receive ductoscopy with either methylene blue or wire marking of the lesion before microdochectomy. Patient clinical characteristics and surgical outcomes were evaluated.

RESULTS: There were 28 patients who received methylene blue marking and 25 who received wire marking of the lesions. There were no differences between the demographic or clinical characteristics of the groups. Wire marking was associated with less surgical time, smaller incisions, and smaller surgical specimens, but the same diagnostic accuracy.

CONCLUSIONS: Wire marking of lesions for microdochectomy is associated with less dissection and tissue damage than methylene blue, yet the same diagnostic accuracy.

Spontaneous nipple discharge (SND) is a common clinical manifestation of breast diseases, and is seen in up to 10% of women who undergo routine examinations.[1] Milky discharge usually represents galactorrhea, and is considered nonpathologic. The most common cause of pathologic SND, which is typically serous or bloody, is intraductal papilloma and is present in approximately 40% of cases.[1] In women who undergo surgical evaluation of SND, occult malignancy is found in up to 20% of cases.[2–4] Nipple discharge typically is evaluated by microscopic examination of discharge smears, ductography, and ultrasonography; however, the diagnostic accuracy of these methods is not high.[5] Definitive diagnosis in most cases requires surgical duct excision (microdochectomy).

In 1988, Teboul[6] first reported the application of ultrasound-guided endoscopy for the observation of breast lesions within the duct lumen. In 1991, Okazaki et al[7] developed an ultrafine fiberoptic ductoscope with a diameter of .45 to .75 mm that enabled direct observation of the breast ducts. With the continuous improvements over the past 2 decades, the breast ductoscope has been reduced in size so that now it can be inserted as deep as class IV or V ducts to identify lesions that cannot be found with other tests,[8,9]

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and potentially diagnose breast cancer earlier than other methods.[10]

Traditionally, microdochectomy has been guided by methylene blue injection through the mammary ducts. However, localization by methylene blue often is inaccurate, which results in a large amount of tissue dissection and damage during surgery.[11] In recent years, investigators have reported that a wire placed via the ductoscope preoperatively into the duct with the lesion aids in the intraoperative identification of the lesion during selective microdochectomy, and can reduce the amount of dissection required.[12] However, it was unknown whether wire marking causes adverse effects, is as effective as methylene blue marking, and can effectively reduce the tissue damage from dissection in selective microdochectomy. Thus, the purpose of our randomized controlled trial in patients who received ductoscopy examinations in our hospital as a result of nipple discharge was to compare methylene blue marking and wire marking in the surgical treatment of intraductal lesions.

Materials and Methods

Subjects

A total of 178 patients received ductoscopy examinations in our hospital for the evaluation of nipple discharge from April 2008 to July 2009. Patients were recruited for inclusion in the study if they had the following: (1) a breast tumor requiring surgical biopsy was identified by ductoscopy, (2) the lesion was limited to a single duct, (3) did not have serious damage in their important internal organs and could receive local anesthesia during surgery, and (4) the patient agreed to participate in the study. Patients were excluded from participation if the following occurred: (1) no lesion was found under ductoscopic examination, (2) multiple tumors were found in multiple mammary ducts or bilaterally in the breasts, and (3) the patient did not require surgical treatment or declined to participate in the study. The study was approved by the institutional review board of our hospital and informed consent was obtained from all participants.

A total of 53 patients were included in the study. Based on the order in which the patients received ductoscopy and a table of random numbers, 28 patients with even numbers received conventional selective microdochectomy guided by methylene blue injection and 25 patients with odd numbers received a selective microdochectomy guided by ductoscopy wire marking.

Patients older than age 40 with a family history of breast cancer also received a mammography examination if it was necessary for clinical diagnosis. In addition, 42 patients underwent a color Doppler ultrasound examination and the rest undone because of personal reasons.

Ductoscopy

All patients received ductoscopy examinations while in the supine position (.8 mm of sheath, 80 mm length, fiberoptic ductoscopy; Schoelly Fiberoptic, Denzlingen, Germany). The breast was cleaned with conventional disinfection and covered with a sterile drape. A size 4.5 flat needle was inserted into the duct and .2 to .4 mL of .5% ropivacaine was injected for local anesthesia. The discharged mammary duct was gradually expanded with numbers 5 to 10 duct dilators. Then, the ductoscope was inserted into the mammary duct and saline was injected into the duct to keep the duct expanded. The ductoscope then slowly was advanced through the duct to observe the wall structure and lumen of the breast sinus and all lower levels of the duct. If abnormalities were found, their characteristics were observed and images were obtained for further analysis.

Selective microdochectomy with methylene blue

After identification of a lesion during ductoscopy, methylene blue was injected into the discharged mammary duct. Local anesthesia was injected into the area to be dissected, and an incision was made around the areola. The skin was separated and the pathologic duct was isolated based on the blue-stained tissue. The pathologic duct was dissected and excised. The incision was closed in a usual fashion.

Selective microdochectomy with ductoscopy wire

After identification of the lesion during ductoscopy, the ductoscope was withdrawn from the sheath and a marking wire (Promex Technologies, St Franklin, IN) was placed to identify the lesion. The wire was fixed with the barb, the sheath withdrawn, and the tail of the wire was left extending from the pathologic duct.

Local anesthesia was injected into the area to be excised, and an incision was made around the areola. The skin was separated and the pathologic duct was isolated based on the position of the wire. The pathologic duct was dissected and excised. The incision was closed in a usual fashion.

Pathologic examination

Because the shape of resection specimen was irregular, the sample size was compared by the longest diameter, which was from the proximal end to the distal end of the dissected duct. Routine hematoxylin-eosin staining and histopathologic examinations were performed for all specimens.

Statistical Analysis

Continuous data were presented as the mean ± standard deviation, whereas nonparametric data were presented as