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Review article

Advances in fibreoptic ductoscopy for the diagnosis and treatment of pathologic papillary overflow

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ABSTRACT

Fibreoptic mammography is widely recognised as the first screening method for pathologic papillary overflow due to its significant advantages in the diagnosis of ductal dilatation, intraductal papilloma and intraductal carcinoma. The use of fibreoptic ductoscopic excisional biopsy techniques, such as biopsy needles, vacuum negative pressure aspiration, biopsy forceps and grasping baskets, has not been promoted largely due to their existing deficiencies. The imaging effect of fibreoptic ductoscopy compared with electronic ductoscopy is also one of the important factors limiting the progress of microscopic excisional biopsy techniques. Finding a more suitable operating space for electronic fibreoptic ductoscopy and the use of electrosurgical excision biopsy techniques should be the focus of research in view of achieving accurate diagnoses in electronic fibreoptic ductoscopy and microscopic excision biopsy. In this review, the development history, clinical application and existing problems of fibreoptic ductoscopy are reviewed and assessed to provide references for the clinical diagnosis and treatment of pathologic papillary overflow.

1. Introduction

Fibreoptic ductoscopy was developed based on other fibreoptic endoscope techniques. After more than 30 years of continuous technical development and clinical application, medical scientists in Japan, Germany, the United States and China have widely used fibreoptic ductoscopy in the diagnosis and treatment of pathological nipple discharge (PND). Since only 5%–8% of the cases are pathologically confirmed as breast cancer after surgical treatment due to PND [1,2], it is possible to avoid excessive surgical treatment for predominantly benign ductal dilatation and intraductal papilloma (IP) [3,4]. Breast ultrasound, X-ray examinations and magnetic resonance imaging (MRI) are all important screening tools for PND; however, the sensitivity of the first two is low [5], while breast MRI has insufficient specificity [6,7] and the detection of suspicious lesions still requires puncture biopsy or surgical excision for definitive diagnosis [8,9]. The specificity of breast ductoscopy for the diagnosis of intraductal carcinoma is 92 %, which significantly improves on the negative diagnosis of breast cancer reached via conventional ultrasound and mammography [10]. Ductoscopy results have been recommended as Class A evidence in the Chinese Society of Breast Surgery 2021 edition of clinical practice guidelines for IP [11],

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resulting in the widespread use of ductoscopy and leading to an unprecedented level of diagnosis and treatment of intraductal occupancies. However, the limitations of the human nipple ductal opening and the width of the internal diameter make it impossible to use electronic ductoscopic imaging techniques or other endoscopic biopsy techniques in the ducts, which has become the fundamental factor limiting the further improvement of ductoscopic diagnosis and biopsy techniques. The current clinical application of fibreoptic ductoscopy generally involves a diameter of 0.75 mm and a resolution of 3000–6000 pixels, while the finest electronic ductoscope that can be produced in the factory is 1.5 mm with a resolution of 150,000 pixels. While the diameter of the latter is twice that of the former, the imaging effect of the latter is 20–50 times that of the former [12,13]. Breast ductoscopy offers the advantages of accurate localisation of pathology, ductal lavage under direct visualisation and intraoperative guidance, especially for lesions deep within the ductal system. Breast ductoscopy with cell biopsy needles, anterior opening biopsy needles, biopsy forceps and grasping baskets are all approaches for breast ductoscopic excisional biopsy, but all have many shortcomings that have led to a compromised diffusion of the technique.

In this article, we look at the historical process of breast ductoscopy and endoscopic development, as well as the clinical application (biopsy technique, ablation treatment, electric excision) and prospects of breast ductoscopy, to illustrate the problems related to this approach and how a breakthrough could be achieved.

2. History of fibreoptic ductoscopy

In 1988, the French researcher, Teboul [14], was the first to use a rigid scope with an outer diameter of 1.7 mm modified by arthroscopy to visualise intramammary duct lesions under ultrasound guidance. Subsequently, Makita et al. [15] improved Teboul's rigid lactoscope with a 1.25-mm reduction in outer diameter. In 1989, Okazaki et al. [16], in collaboration with Fujikura Corporation, successfully developed a fibreoptic ductoscopy system (FDS) for diagnosis and treatment, with a diameter designed in two sizes, 0.45 and 0.8 mm, the former for distal branch ducts and the latter for proximal main ducts. During the operation, a 0.35-mm tear duct probe was first used to dilate the opening of the milk duct to reach 0.45–0.50 mm before a lactoscope was inserted for intramammary duct examination. Subsequently, Okazaki et al. performed ductoscopy in 46 patients with PND between August 1989 and June 1990. The examination failed in five cases, and 47 ducts were examined in 41 successful cases, of which 14 ducts in 13 patients were operated on, with postoperative pathology of four cases of breast cancer, eight cases of IP (nine ducts) and one case of mastitis. Okazaki et al. noted that the FDS was able to detect microscopic lesions in the breast ducts and further diagnose and evaluate intraductal papillary carcinoma. Since then, the FDS has gradually been recognised and promoted worldwide.

Six years later, the Cancer Hospital of Fudan University in Shanghai [17], Guangdong Women's and Children's Hospital [18] and Beijing Chaoyang Hospital of Capital Medical University [19] were the first to introduce fibreoptic ductoscopy technology into China and immediately conducted diagnostic, exfoliative cell lavage, excisional biopsy and indwelling positioning guidewire-hook-catheter work.

3. The development of electronic fibreoptic ductoscopy

Since its emergence in 1806, the subsequent 200 years of the development of electronic fibreoptic ductoscopy has mainly involved the hard tube endoscope, semi-flexible endoscope, fibre optic endoscope and four-stage electronic endoscope techniques, among which the fibre optic endoscope and electronic endoscope techniques are the two most important.

The endoscope system is generally divided into three major parts: the speculum system, the image system and the illumination system. In 1806, Philipp Bozzini (1773–1809) of Vienna invented the first endoscope, which consisted of a vase-shaped light source, a candle and a series of lenses, the candle being the source of illumination for the endoscope. In 1932, Schindler collaborated with Wolf, a medical device engineer, to develop the Wolf–Schindler endoscope, which was called a semi-flexible endoscope because the front end of the mirror could be bent and flexed to allow access to the curved part of the stomach, meaning the structure could be clearly observed. flexion endoscope. The above three endoscopes use candles or light bulbs as the lighting source and the effect is poor, with image distortion and burns to the examined tissue easily occurring, meaning that, at this point, the endoscope was not accepted by everyone.

In 1957, the world's first gastric and duodenal fibreoptic endoscope was successfully developed by Hirschowitz, which quickly gained recognition due to the use of fibreoptic fibres for light guidance and image transmission, resulting in good illumination, clear images and easy bending of the mirror body, while the technique was effective in avoiding burns to the examined tissues. At this stage, endoscopes were not only used for microscopic diagnosis of gastrointestinal diseases but were also widely used for the treatment of such diseases, including in terms of haemostasis of the upper gastrointestinal tract, stent placement for gastrointestinal strictures, microscopic laser treatment of gastrointestinal tumours, gastrostomy and empty-field stoma to resolve intestinal nutrition, duodenal papillotomy for stone extraction due to common bile duct stones with obstructive jaundice and gastrointestinal polyp removal.

In 1983, Welch Allyn Company of the United States successfully developed the micro image sensor (charge-coupled device) and applied it to the endoscopy system, thus marking the birth of electronic endoscopy. Compared with the ordinary optical fibre endoscope, the image clarity and colour reproduction of the electronic endoscope was far superior, and from this point on, the digestive endoscope system entered a rapid development stage.

High-resolution electronic endoscopes and infrared electronic endoscopes were among the products of this stage. Among them, the miniature ultrasound probe used in ultrasonic electronic endoscopy is only 2.0 mm in diameter and has a frequency of 7.5–12 MHz, which extends the scope of gastrointestinal endoscopy diagnosis and intervention from the mucosal layer of the digestive tract to the whole layer of the digestive tract and the surrounding tissues of the digestive tract.

On reviewing the history of medical endoscopy, the emergence of fibreoptic and electronic endoscopy has clearly played a crucial role. Electronic fibreoptic ductoscopy was developed on the basis of fibreoptic endoscopy. However, despite the availability of electronic fibreoptic ductoscopy technology, due to the opening of the human milk duct and the limitation of the internal diameter of the milk duct itself, even the thinnest probe (1.5 mm in diameter) cannot be used in clinical practice, which is the fundamental reason that electronic fibreoptic ductoscopy technology has not gone beyond the stage of fibreoptic lactoscopy.

4. Breast ductoscopic biopsy technique

Excisional biopsy of intraductal occupations in the breast ducts is an important goal of ductal work, as is diagnosis via ductoscopy. Exploration of the biopsy and excision of intraductal lesions in the breast ducts via ductoscopy remains ongoing.

4.1. Tube curette cytology

The first report on the use of the tube curette cytology (TCC) technique for excisional biopsy of IP in China was by Prof. Chip Wang's team at Guangdong Women's and Children's Hospital, who completed the excision of five cases of single IP in 2003 [20]. Prior to surgery, a lactoscope was used to cross the IP and explore the distal milk ducts to exclude multiple IPs, while repeated cuts were made via TCC under lactoscopic surveillance and the specimens were collected using negative pressure aspiration with a 10-ml syringe. The results were successful in four lesions ≤1 mm in diameter, and no recurrence was seen during the subsequent follow-up period of 1–6 months. Unsuccessful surgery occurred with one lesion measuring 2 mm in diameter, which involved a large incision and bleeding, resulting in poor visualisation and haemorrhage recurrence 2 months after surgery; the approach was thus converted to segmental mastectomy. The operators' experience is that TCC for IP excisional biopsy is suitable for IP lesions up to 1.0 mm, which require repeated multiple cuts because of the small cutting effectiveness and difficulty; for IP lesions larger than 1.0 mm, there may be some residual. In addition, specimen collection is difficult and larger tissue specimens are not easily available. For IP with atypical hyperplasia on pathology, routine surgery or close follow-up is recommended.

4.2. Intraductal breast biopsy

The intraductal breast biopsy (IDBB) device is a biopsy device with a side hole near the tip, with the edge of the side hole designed with a sharp edge that can act as a cutting edge on the tissue. During the IDBB procedure, the IDBB trocar needs to be placed on the outside of the ductoscope and then inserted into the duct with the ductoscope. When a swelling is seen in the duct, the swelling needs to be placed into the IDBB side hole and the IDBB is then rotated to remove the swelling before the ductoscope and IDBB trocar are withdrawn to collect the specimen (Fig. 1A and B).

In 2004, Professor Tadaharu Matsunaga [21] first reported IDBB surgery using an anteriorly open ductal needle under mammography. Here, mammography was performed in 295 patients with nipple discharge and 30 intraductal carcinomas (from a total of 27 patients) were found, 36 IDBB procedures were performed and 21 diagnostic specimens were obtained, with a success rate of 58.3 %. In addition, in 75 Ips (from a total of 70 patients), 54 IDBB procedures were performed successfully, with a success rate of 77.6 %. Overall, the success rate of IDBB procedures is not particularly high and the results are not satisfactory.

To obtain better histological specimens of intraductal occlusions, Professor M. Hunerbein's team [22] developed an intraductal vacuum-assisted biopsy needle (0.9 mm in diameter) using a rigid 0.7-mm-diameter mammoscope, which is attached to the mammoscope with a lateral opening at the tip and a cutting blade; this is in contrast to Professor Tadaharu Matsunaga's IDBB. The difference with Prof. Matsunaga's IDBB lies in the design of a vacuum suction device with a hose at the end of the mammoscope, which facilitates the smooth removal of the specimen (Fig. 2A and B). The team successfully performed ductoscopy in 37 of the 38 (97 %) patients with nipple discharge between 2002 and 2005, and 29 (78 %) of these patients were diagnosed with an intraductal occupying

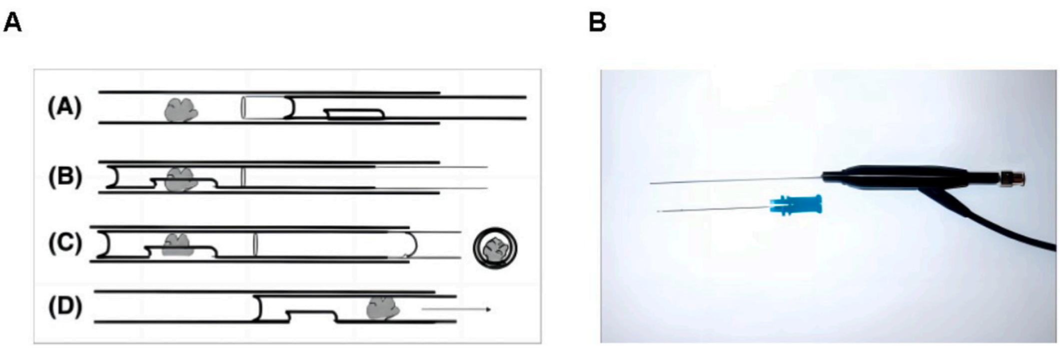

Fig. 1. A. Schematic diagram of IDBB procedure; B. Lactoscope and IDBB biopsy needle (Picture Source: Matsunaga T, Kawakami Y, Namba K, Fujii M. Intraductal biopsy for diagnosis and treatment of intraductal lesions of the breast. Cancer. 2004 Nov 15; 101 (10):2164–9. https://doi.org/10.1002/cncr.20657.).

lesion. When vacuum-assisted biopsy was performed, it was successful in 28 cases and diagnostic biopsy specimens were obtained in 26 (93 %), including 22 cases of papilloma, two of in-situ carcinomas and two of invasive carcinomas. The authors noted that ductoscopic vacuum-assisted biopsy is a new technique for excisional biopsy of diseased tissue in the breast ducts, but that ductoscopy cannot be used as a means of early breast cancer screening because it does not reach all distal branch ducts. Although the success rate of 93 % for ductal occupancy biopsy in the above study is certainly promising, the sample size was comparatively small and no other scholars have subsequently reported similar results in this regard.

4.3. Biopsy forceps under breast ductoscopy

In 2008, Shao et al. [23] first reported the application of the LS2000 breast ductoscope (PolyDiagnostGmbH, Pfaffenhofen, Germany) manufactured by the German company, Shelley, with an external diameter of 1.1 mm and three channels for biopsy forceps. The biopsy forceps are the lactoscope accessories produced by Shelley, which include the head of the forceps and the tail of the two-part wire and the head of the blunt round. During biopsy, the head of the forceps bites into the lesion and then rotates and applies backward pressure to 'tear' the specimen under the surveillance of the lactoscope. The obtained specimens were processed separately according to size, with histopathology performed on specimens >1.0 mm and cytopathology performed on specimens <1.0 mm. Between May 2006 and April 2007, the team performed 53 breast ductoscopic biopsies with biopsy forceps in 51 patients with intramammary duct occupations, with a success rate of 90.6 % (48 cases). The reasons for failure were: (1) the intraductal site was too close to the nipple opening and there was no room for operation; and (2) the intraductal site was located in a branch breast duct and the lumen was too narrow for the lactoscope to pass through. Due to the blunt round head of the biopsy forceps under lactoscopy, the forceps could only bite the lesion protruding from the wall of the duct, which means the surgical goal of 'excision of the lesion' is still some distance away. In addition, the small volume of specimens obtained via forceps biopsy leads to an underestimation of the benignity and malignancy of the intraductal lesion, meaning further surgical excision of the diseased duct is required to exclude malignancy.

4.4. Extraction using basket excision

In 2009, in Turkey, Ömer Bender [24] performed a ductoscopic papilloma basket excision procedure using a German LaDuScope ductoscope. All patients were first examined using papillary overflow smear and ductal lavage, and if the cytology was negative and the papilloma was tipped in the milk duct, ductoscopic papilloma basket excision was performed. Here, all or part of the ductoscopic papilloma basket resection is accomplished by first moving the distal end of the 380-μm basket to the lesion via the working channel before opening the basket and then rotating and moving it back and forth (Fig. 3). For positive cytology (malignant or anisocytic cells are seen) or for negative cytology where the papilloma in the milk duct is anaplastic, open surgery of the diseased milk duct and distal lobule assisted by electronic fibreoptic ductoscopy is performed. The authors applied the ductoscopic basket excision technique to 34 cases of solitary IP with a success rate of 79.4 % (27 cases), of which 21 cases were completely excised and six were partially excised (<10 % of the remaining tumour was completely excised and >10 % was partially excised). Among the seven failed cases, six lesions were left in the breast ducts because the tumour was too large to be removed successfully, and one was too small for the basket to be ligated accurately. This is in general agreement with the findings of Waaijer et al. [25] and Kamali et al. [26]. The size of the tumour can make ductal basket resection unfeasible if the tumour is too large to block the lumen or too small to be ligated successfully.

5. Ablation treatment under breast ductoscopy

The first laser ablation study was conducted as early as 1994 by Harries et al. [27]. The study included 44 patients and treatment was performed under ultrasound guidance in 42 patients and computed tomography guidance in two using a semiconductor laser with

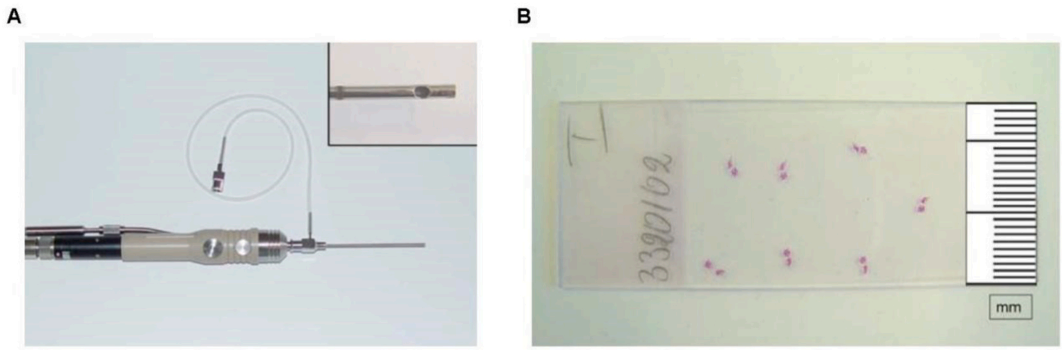

Fig. 2. A. Rigid ductoscope and intramammary vacuum-assisted biopsy needle. B. Pathological histological section of biopsy specimen obtained using vacuum-assisted biopsy needle. (Picture Source: Hünerbein M, Raubach M, Gebauer B, Schneider W, Schlag PM. Ductoscopy and intraductal vacuum assisted biopsy in women with pathologic nipple discharge. Breast Cancer Res Treat. 2006 Oct; 99 (3):301–7. https://doi.org/10.1007/s10549-006-9209-9.).

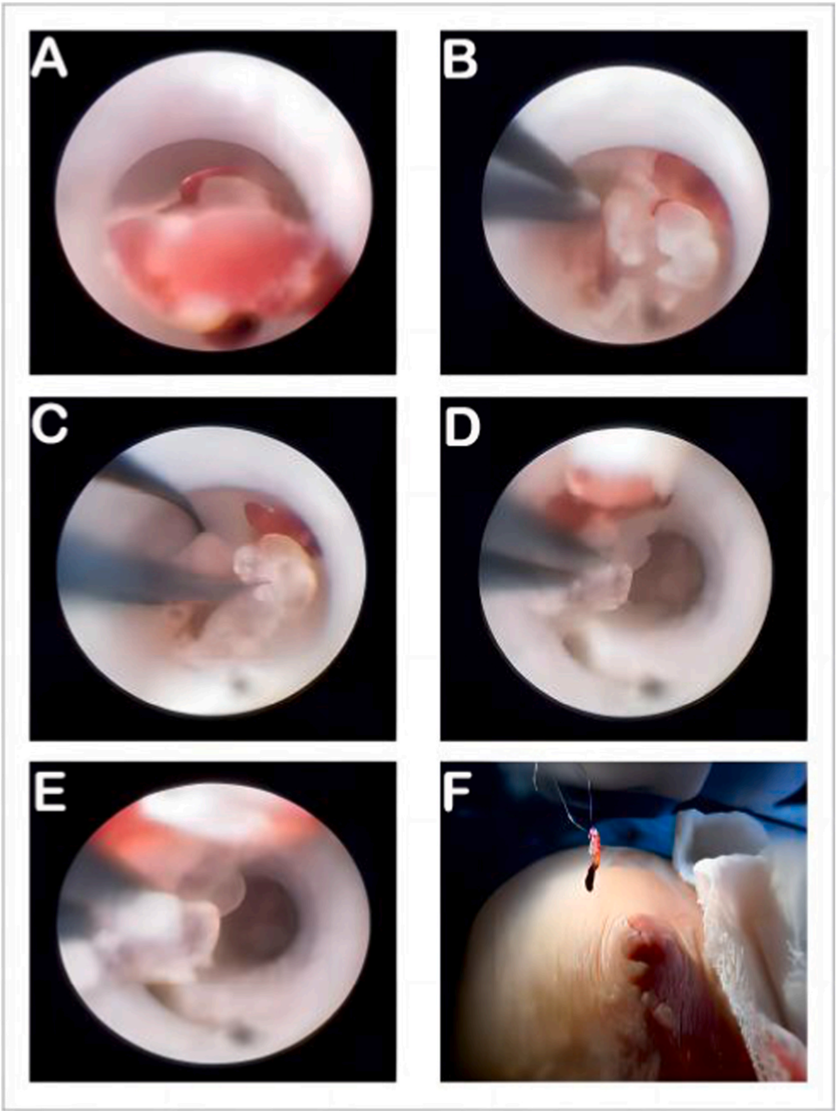

Fig. 3. Papilloma extraction by basket under breast ductoscopic. A. The location of the lesion was observed under breast ductoscopic. B. The basket was moved forward distally to the lesion. C. The basket was opened. D. The basket was rotated. E. The basket moved back to extirpate and remove the lesion. F. The removed lesion was shown. (Bender O, Balci FL, Yüney E, Akbulut H. Scarless endoscopic papillomectomy of the breast. Onkologie. 2009 Mar; 32 (3):94–8. https://doi.org/10.1159/000195694.).

a wavelength of 805 nm and a 400-μm fibre. The tumour was treated for 500–750 s with a power of 2–3 W. Necrosis within the excised tumour varied from 0 to 2.5 cm and excision was performed after 1–34 days. Due to the technical difficulties of using the device and targeting the correct area, interest in the technique waned. However, the development of more sophisticated and reliable lasers and the use of more flexible and better-quality guiding systems has resulted in renewed interest.

In 2022, Makineli et al. [28] from the Netherlands conducted a single-centre prospective study to evaluate the effectiveness of three new approaches in patients with intraductal breast lesions (pre-cancerous), namely, narrow-band imaging (NBI), a method involving new intraductal biopsy tools and intraductal laser ablation. The first, NBI, is a technique that uses a different spectrum to mark suspicious lesions. Following activation of NBI, the blood vessels on the surface of the tumour tissue appear dark, thus improving the visibility of the tumour tissue and the identification of its surface structures. Although NBI has been widely used in gastrointestinal endoscopy, its use in breast ductoscopy has not been reported, while studies have confirmed that NBI shows different vascularisation patterns between healthy breast tissue and breast cancer tissue [29–31]. To improve the effectiveness of breast ductoscopic biopsy, the group developed new breast ductoscopic biopsy tools and tested them regarding their suitability for biopsies and their ability to accurately excise occupying lesions in the breast duct. In addition, for occupying lesions in the milk ducts, the group aimed to first perform a biopsy using the newly developed ductoscopic biopsy tools before using a laser to ablate the biopsy remnants and smaller flat lesions. The use of lasers in other areas of clinical medicine has proven to be effective in ablating tissue [32], while in-vitro trials involving laser ablation under breast ductoscopy have also confirmed this to be a feasible approach [33]. Taken together, the results of this project are well worth waiting for.

6. Electric excision under breast ductoscopy

Among the aforementioned techniques of mammary ductoscopic excisional biopsy, the use of mechanical principles to excise occupying lesions in the milk duct is the predominant method, and although lasers can ablate the diseased tissue in the milk duct, there is a fundamental distance from the surgical category of 'excisional biopsy'. The role of energy platforms such as electric and ultrasonic knives in the field of surgery is undeniable; however, the limited space in the breast duct has led to a major limitation in the clinical application of patented products such as mammoscopic sheath electrodes [34], which may inspire us to think about the solution from another perspective.

7. The positioning guide wire was placed under the guidance of fiberoptic ductoscopy for accurate resection

Lesions For the patients with space-occupying lesions found under fiberoptic ductoscopy, it has been reported that most of them are treated with Meilan dye for legal site resection, but this method pollens the surgical field and has a large resection range, which makes it impossible to achieve accurate resection [35,36]. Instead, positioning guides are placed under the guidance of fiberoptic ductoscopy, and the quadrant where the lesions are marked on the body surface and the length of distance from the nipple during fiberoptic ductoscopy. At the same time, the outer sheath of the guide wire is placed at the location of the guide wire during the operation. The location of the outer sheath can be explored during the operation to avoid the excessive and inaccurate probe of the guide wire, so as to achieve the purpose of accurate resection of the lesion. (Table 1).

8. Limitations of the technique

While fibreoptic ductoscopy provides useful information about the catheter system, the approach still has its limitations. While fibreoptic ductoscopy typically examines 1–2 catheters per breast, the remaining catheters are not examined, and it is not known whether these are the most common sites where tumours occur [37]. Fibreoptic ductoscopy allows for observing the milk duct, milk sinus, segmental milk duct and its main branches directly. However, the technique's ability to directly observe small-diameter peripheral duct lesions and determine the extent of malignant lesions is limited by the complex branching pattern of breast ducts, thus limiting the sensitivity of this technique [38]. Lumen obstruction due to disease, scarring or sclerosis, pseudocatheter formation and acute angulation of catheter branches are recognised causes of failure in distal catheterisation [39].

9. Future prospects

Electronic fibreoptic ductoscopy is an effective tool for the diagnosis and treatment of intraductal disease. The technique was developed based on fibreoptic endoscopy, and effectively increases the chances of diagnosing and treating PND through open surgical

Table 1
Electronic fiberoptic ductoscopyclinical application.

Number	Application	Method	Classification	Condition	Remarks
01	Fibrobreastoscopy for pathological nipple discharge	Class I-IV milk ducts, direct microscopic diagnosis; distal terminal milk ducts, lavage fluid exfoliation cytology	Fiberoptic ductoscopy	clinical application and promotion	
02	Fibro-mammoscopic excisional biopsy of an occupying lesion in the milk duct	1. cell biopsy needle biopsy. 2. anterior open window catheter needle intraductal biopsy. 3. vacuum negative pressure aspiration biopsy. 4. biopsy forceps biopsy. 5. Mesh basket biopsy	Fiberoptic ductoscopy	clinical application without promotion	
03	Fibro-mammoscopic ablative resection of an occupying lesion in the milk duct	Laser ablation Electroexcision biopsy	Fiberoptic ductoscopy	clinical application without promotion	
04	Fibro-mammoscopic excisional biopsy of intramammary duct occupying lesions	Laser ablation Electroexcision biopsy	Fiberoptic ductoscopy	No clinical application	Need more space for milk ducts
05	Electronic mammography for pathological nipple discharge	Class I-IV milk ducts, direct microscopic diagnosis; distal terminal milk ducts, lavage fluid exfoliation cytology	Electronic Lactoscope	No clinical application	Need more space for milk ducts
06	Electrospectomy biopsy of occupying lesions in the milk ducts	Electrodesiccation biopsy under electron ductoscopic	Electronic Lactoscope	No clinical application	Need more space for milk ducts
07	Positioning under the fiberoptic ductoscopy	Accurate resection	Fiberoptic ductoscopy	clinical application and promotion	

procedures. However, the narrow space in the milk ducts makes electronic mammography unusable, and the imaging effect of mammography can only continue to remain at the level of fibreoptic mammography. Furthermore, this issue also leads to a certain degree of inherent deficiency in all existing mammoscopic excisional biopsy techniques, making it difficult to fully meet the needs of clinicians. Developing a new type of ductal expansion device, expanding the limited space in the duct or creating a new approach to mammography may lead to a breakthrough. The development of a biopsy kit that allows for adequate microbiopsies for histological diagnosis is likely to enhance the role of MD in breast cancer screening among high-risk women and reduce the need for duct excision in patients with PND due to benign disease.

Ethics approval and consent to participate

An ethics statement is not applicable because this study is based exclusively on published literature.

Consent for publication

Not applicable.

Data availability

There is no research related data stored in publicly available repositories, and the data will be made available on request.

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CRediT authorship contribution statement

Xiang Fei: Writing - review & editing, Writing - original draft, Formal analysis, Data curation. **Wei Yong:** Writing - review & editing, Writing - original draft, Formal analysis, Data curation. **Dongxiao Zhang:** Writing - review & editing, Writing - original draft, Formal analysis, Conceptualization. **Jianchun Cui:** Writing - review & editing, Writing - original draft, Visualization, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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