

Clinical efficacy of fiberoptic ductoscopy in combination with ultrasound-guided minimally invasive surgery in treatment of plasma cell mastitis

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Summary

Objectives: To analyze clinical efficacy between fiberoptic ductoscopy plus ultrasound-guided minimally invasive irrigation and lesion resection in treating plasma cell mastitis (PCM), aiming to provide clinical evidence for treating PCM. **Materials and Methods:** 119 patients undergoing fiberoptic ductoscopy plus ultrasound-guided minimally invasive surgery in Ningxia People's Hospital were allocated into the breast duct irrigation group, and 95 counterparts receiving lesion resection in the Affiliated Hospital of Ningxia Medical University into the control group. Clinico-pathological characteristics and therapeutic effect were compared between two groups. **Results:** The cure rate in the breast duct irrigation group was 98.31% (117/119), significantly higher than 90.53% in the control group ($p < 0.05$). In the breast duct irrigation group, overall treatment time was 20.13 days, significantly longer than 15.15 days in the control group ($p < 0.05$). During postoperative follow-up, no recurrence was observed, significantly lower compared with 48.8% (42/86) in the control group. The degree of satisfaction in the breast duct irrigation group was 95.79% (114/119), significantly higher compared with 74.74% (71/95) in the control group. **Conclusions:** Fiberoptic ductoscopy plus with ultrasound-guided minimally invasive drainage is a novel and effective treatment of PCM with high cure rate, low recurrence rate, slight pain, and effectively maintains breast integrity.

Key words: Plasma cell mastitis; Surgical operation; Fiberoptic ductoscopy; Minimally invasive drainage; Ultrasonics.

Introduction

Plasma cell mastitis (PCM) is a chronic non-bacterial breast inflammatory disease and mainly occurs during non-puerperal period, which is characterized as duct ectasia and plasma cell infiltration [1]. PCM is probably caused by acute sterile inflammatory response induced by accumulation of lipid secretion in the breast duct [2]. The pathogenesis of PCM is complicated and clinically characterized as breast tumor accompanied with/without topical redness and swelling, inflammatory lesions, mammary areola abscess, mammary duct fistula, etc. The degree of inflammation is inconsistent with clinical symptoms with slight or no systemic symptoms. Along with the progression of pathological changes, the presence of inflammatory responses, dominantly plasma cell infiltration, is defined as PCM. It is likely to make a misdiagnosis of PCM. Traditional surgery yields poor clinical efficacy and high recurrence rate, and is likely to destroy the breast morphology. Albeit combined therapy of fiberoptic ductoscopy and traditional Chinese medicine has been reported recently, the clinical efficacy remains elusive. A total of 119 patients pathologically diagnosed by PCM cell smears or core needle biopsy in Department of Breast Surgery, Ningxia People's Hospital between June 2011 and June 2013 were enrolled in this study. All participants underwent fiberoptic ductoscopy irrigation and minimally invasive

drainage (abbreviated as breast duct irrigation group). Another 95 PCM cases were surgically treated with lesion resection in the Affiliated Hospital of Ningxia Medical University (control group). The therapeutic effect was retrospectively analyzed and statistically compared between two groups, is reported.

Materials and Methods

General data

Clinical data of 119 PCM patients in the breast duct irrigation group were collected including two married males, 117 female (three single, three pregnant, eight married but nulliparous, and 105 lactation), aged 12-47 years, with a median age of 36 years. Among them, 49 (41.18%) were affected on the left side, 63 (52.94%) on the right side, and seven (6%) with bilateral involvement; 112 cases (94.12%) had single lesion and seven (6%) presented with multiple lesions. Yellow or gray turbid discharge was observed in 87 patients (73.11%) and no discharge found in the remaining 32 cases (26.90%). The course of diseases ranged from 11 d to four months, 32 days on average. Eighty patients (67.23%) had inverted nipple and 27 presented with breast masses (mammary areola masses in 20 and peripheral masses in seven) and 43 had pus; 12 patients presented with single fistulization and five had fistulization in over two sites. Seventy-nine patients (66.39%) had surgical history of tumor excision. Two cases were subject to inverted nipple correction, 23 (19.33%) were taking traditional Chinese medicines for over three months, and one received acupuncture for more than two months.

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Another 95 PCM cases surgically treated with lesion resection in the Affiliated Hospital of Ningxia Medical University were assigned into the control group, 93 female and two males, 37 years on average. The gender, age, obstetrical history, type of pathological changes, and course of diseases were matched between two groups ($p > 0.05$). The time of follow-up ranged from six to 36 months in both groups. This research protocol was approved by the Ethics Committee of Ningxia Medical University before the study was initiated. Written informed consents were obtained from all participants in this study.

Treatment methods

Breast duct surgery: The diagnostic criteria were determined according to the staging of disease development [3]: stage I effusion accumulated in the breast duct; stage II masses formed; stage III pus accumulated in the lesions; stage IV formation of skin ulceration sinus tract. Different therapies targeting each stage were performed and rehabilitation treatment was delivered subsequently. (1) Thirty-two cases with mammary duct ectasia effusion were treated with fiberoptic ductoscopy irrigation alone. (2) For patients with gray or yellow discharge in the nipple, B-ultrasound revealed signs of punctuate strong echo in the breast duct ectasia of the masses. Slight migration was sensed under probe compression. Twenty-seven cases had inactive primary inflammatory tumors characterized with no envelope, unclear margin and gland edema, and underwent fiberoptic ductoscopy irrigation under direct vision. (3) Forty-three patients with breast abscess were subject to fiberoptic ductoscopy irrigation in combination with minimally invasive drainage irrigation. Approximately two to ten syringes were implanted guided by B-ultrasound based on single or multiple abscess, making the injection and outflow in synchronization. The depth and position of the syringes were adjusted based on B-ultrasound monitoring and the resistance of injection and outflow to guarantee thorough drainage of abscess, accelerate wound healing, and avoid the formation of sinus tract. No formation of sinus tract occurred in 43 patients with breast abscess throughout the whole treatment. (4) Seventeen cases with breast duct fistula were treated with fiberoptic ductoscopy irrigation in combination with minimally invasive drainage irrigation. The normal skin surrounding the ostia was chosen as the site of needle implantation rather than sinus tract opening for patients with formation of sinus tract. The ostia was selected as the opening of outflow. After irrigation, moist burn ointment (MEBO) was daubed and sterile honey were daubed on the ostia to accelerate ostia healing. The depth and thickness of retained syringe were adjusted based upon B-ultrasound findings, depth, and diameter of the sinus tract. Seventeen patients presenting with sinus tract formation were all completely healed, whereas the course of treatment was significantly longer compared with their counterparts in abscess and tumor stage.

Fiberoptic ductoscopy irrigation: ornidazole or 0.9% sodium chloride solution was injected through the discharge hole to dilute the substance accumulated in the breast duct. For those with crystal formation, melting chymotrypsin was injected for 15-minute perfusion and then discharged. The frequency of irrigation was determined based upon the property and quantity of the substance accumulated in the breast duct. Patients with a slight amount of accumulated substance received single irrigation. Those with a large amount of sticky and even crystal substance were subjected to two to three times irrigation. The syringe was kept for irrigation: the position of the catheter was validated according to B-ultrasound findings before irrigation.

Irrigation sequence: the syringe needle was inserted into the needle plug and the discharge was removed using 0.9% sodium chloride solution to avert the incidence of retrograde flow, and then the syringe was inserted into the needle plug and 0.9% sodium chloride solution, 0.5% ornidazole and 80,000 units of gentamicin were in-

Table 1. — Comparison of course of treatment between two groups.

Group	N. of cases	Total time of treatment (days)	t-value	p-value
Breast duct irrigation group	119	20.13± 5.32	9.24	0.000
Control group	95	15.15± 2.24		

jected into the lesions in sequence. During the process of irrigation, the condition of cavity was monitored under B-ultrasound, the injection resistance was sensed by hands, and the degree of outflow was observed by vision. Whether the syringe was retained depended upon the size of cavity, the brightness, and quantity of effusion.

During the entire course of treatment, partial patients presenting with fever and worsened inflammation during the early stage of PCM were administered with penicillin, combined with ornidazole via intravenous injection. Immunity enhancers, such as thymosin, traditional Chinese medicine which removes the heat and toxicity and systemic treatment, were delivered during topical perfusion and irrigation.

Lesion excision: Sixteen patients underwent breast lobe resection, 29 topical wedge resection, 31 excision and drainage of abscess, five simple mastectomy, and 14 resection of chronic sinus tract and fistula.

Statistical analysis

SPSS 13.0 software package was utilized for statistical analysis in this study. Measurement data were expressed as mean ± standard deviation. The overall time of treatment was statistically compared between two groups by independent sample *t*-test and enumeration data were statistically compared by chi-square test. The ordinal data were analyzed by rank-sum test. A $p < 0.05$ was considered as a statistical significance.

Results

Total time of treatment

The total time of treatment differed in 119 PCM patients in the breast duct irrigation group: 8, 12, 26, and 41 days for patients in mammary duct ectasia effusion, breast tumor, breast abscess, and breast duct fistula stages, respectively. The mean total time of treatment was 20.13 days, significantly longer compared with 15.15 days in the control group ($p < 0.05$), as illustrated in Table 1.

Therapeutic effect and follow-up

Following breast duct irrigation, 117 patients recovered and two underwent total mastectomy with a cure rate up to 98.3%, significantly higher than 90.53% (86/95) in the control group. Referring to the treatment criteria widely accepted by Chinese physicians [4], the patients eligible for the healing criteria were re-examined by ultrasound test at one week, one, three, six, and 12 months until the registering date (at least one year). In the breast duct irrigation group, merely two cases showed slight topical discomforts, which were alleviated by B-ultrasound-guided suction of turbid residue and repeated irrigation with ornidazole so-

Table 2. — Comparison of clinical efficacy and recurrence rate between two groups.

Group	Treatment efficacy		Recurrence rate	
	Healing (cure rate)	Not healed	Not recurrent	Recurrence (recurrence rate)
Breast duct irrigation group	117 (98.31%)	2	117	0
Control group	86 (90.53%)	9	44	42 (48.84%)
χ^2 -value	5.079		72.046	
<i>p</i> -value	0.024		0.000	

Note: Albeit this therapy has been rarely conducted in China, none of the 117 PCM patients undergoing fiberoptic ductoscopy in combination with minimally invasive drainage recurred during the follow-up with a recurrence rate of 0.

lution. The recurrence rate in the breast duct irrigation group was significantly lower compared with 48.4% in the control group (Table 2).

Postoperative changes in breast shape

According to the criteria evaluation criteria [5], excellent: the treated breast almost resembled the contralateral

Table 3. — Evaluation of postoperative breast deformation between two groups.

Group	No. of cases (n)	Changes in breast shape [(n%)]			
		Excellent	Good	Average	Poor
Breast duct irrigation group	119	34	29	41	15
Control group	95	7	20	37	31
<i>Z</i> -value	4.586				
<i>p</i> -value	0.000				

side in size and shape; good: breast retraction and/or skin alterations involving with $< 1/4$ of the original breast; average: breast retraction and/or skin alterations involving with $1/4$ to $1/2$; poor: breast deformity involving with $> 1/2$. The breast shape in the breast duct irrigation group was significantly superior to that in the control group ($p < 0.05$), as illustrated in Table 3 and in Figures 1-4.

Degree of satisfaction of patients

Self-designed questionnaire was adopted to evaluate the



Figure 1. — PCM patient before breast duct irrigation.



Figure 2. — PCM patient after breast duct irrigation.



Figure 3. — PCM patient before surgical excision treatment.



Figure 4. — PCM patients after operation.

Table 4. — Comparison of degree of satisfaction of PCM Patients between two groups.

Group	No. of cases (n)	Satisfied	Not satisfied	Degree of satisfaction (%)	χ^2 value	P value
Breast duct irrigation group	119	114	5	95.80%	20.003	0.000
Control group	95	71	24	74.74%		

patients' degree of satisfaction. The degree of satisfaction for therapeutic effect, service attitude, and breast shape achieved to 95.8% in the breast duct irrigation group, significantly higher than 74.74% in the control group ($p < 0.05$), as shown in Table 4.

Discussion

Based on the aforementioned results, the cycle of breast duct irrigation was 20.13 days, significantly longer than 15.15 days of lesion excision because different therapies were selected according to the staging and development of diseases in the breast duct irrigation group. In this study, nipple dysplasia, epithelial hyperkeratosis or breast duct occlusion and ischiesis induced by galactostasis, duct ectasia, galactophoritis, chronic granuloma mastitis, and even secondary abscess and fistula were the potential causes and pathogenesis of the development of pathological changes of varying degree [6]. The direct vision and infusion of fiberoptic ductoscopy were fully utilized to directly and repeatedly inject chymotrypsin and ornidazole or 0.9% sodium chloride solution into the cavity and to dissolve and eliminate the ischiesis within the necrotic cavity, which avoided the biochemical reaction aroused by the effusion accumulated in the breast duct and prevented the progression to tumors even the formation of pyogenic sinus tract [7]. The repairing process of the lesions and the integrity of breast healing were fully considered. The present authors suggested that it is more likely to be accepted by the patients as compared with breast tissue defected caused by surgical excision.

In terms of cure rate, recurrence rate and patients' degree of satisfaction, fiberoptic ductoscopy in combination with ultrasound-guided minimally invasive drainage is a rational and reliable therapy. Repeated dissolution and irrigation of the lesions combined with B-ultrasound guided implantation of venous needle can yield accurate and direct drainage and significant advantages in drainage. Establishment of a channel with an injection entry from fiberoptic ductoscopy and an exit from drainage tube is able to maintain the short-term cure rate as high as 98.31%. After healing, the patients should be closely monitored by B-ultrasound during subsequent

follow-up. The effusion accumulated in the breast duct could be fully removed under fiberoptic ductoscopy. The topical residual or new effusion with the diseased cavity surrounding the breast duct could be timely extracted to minimize the recurrence of diseases. However, the lesion may be directly resected by surgical approaches, but the effusion outside the breast duct and the potential lesions in alternative sites could not be fully eliminated, which severely affects the healing of PCM and leads to a high recurrence rate up to 48.84% in the control group of current study. In addition, repeated surgeries cause serious breast tissue defects and distortion.

Compared with conventional surgery, irrigation drainage is a historic revolutionary treatment of PCM from traditional lesion incision and drainage or surgical tissue excision to minimally invasive drainage and tissue healing under fiberoptic ductoscopy with an incision of one to two mm, which significantly alleviates skin injury, tissue defects, and slight scars after healing. More importantly, this technique maintains the integrity if the breast as much as possible. In addition, it causes significantly less pain both physically and mentally compared with surgical incision, drainage, and excision. All these advantages contribute to the high patients' degree of satisfaction, up to 95.80% obtained in this group. Alternative causes possibly included: first, the healing effect was recognized by most patients; second, minimally invasive was widely accepted in modern medicine; third, concentrated therapy offered confidence to patients in persisting the treatment by mutual visit, exchange, comforting, and encouragement. The major limitation is that a slight proportion of patients may give up the therapy due to the relatively long operating time, which remains to be improved by intensive communication with nationwide PCM specialists to obtain valuable clinical experience. The more advanced five-channel tube should be applied in fiberoptic ductoscopy irrigation, which integrates biopsy, vacuum suction of effusion, excision of necrotic tissue, and implantation of drainage tube in one-step procedure and significantly shortens the course of treatment of PCM.

Taken together, previous studies found that the pathogenesis of PCM is the effusion in breast duct, immune hypofunction, anaerobe infection, etc. In this study, the PCM patients underwent fiberoptic ductoscopy irrigation in combination with ultrasound-guided minimally invasive drainage and immunity-enhancing therapy, which corresponds to the underlying pathogenesis. It is equally advantageous in terms of overall clinical efficacy and the integrity of breast morphology, etc. Previous studies demonstrated that surgery is the most radical and effective treatment of PCM [8], whereas it is likely to destroy the breast morphology. In this study, the recurrence rate of PCM in the control group was up to 48.84%, leading to severe psychological pain during daily life. Moreover,

the average age of onset in patients was 36 years. Maintaining the breast integrity not only contributes to building a stable and harmonious family, but also enhances the survival and quality of life of patients. Chinese medicine treatment has also been recommended by certain scholars [9]. However, 19.33% (23/119) of patients in this study were treated with Chinese medicine for six months to two years. One case receiving acupuncture therapy for half a year presented with pyogenic necrosis evolving from redness and swelling. Hence, the clinical efficacy of traditional Chinese medicine in treating PCM remains to be further elucidated. In the current investigation, ultrasonic intervention and guidance played a significant adjuvant role in treating PCM. In particular, compared with traditional "cross" incision and drainage by placement of vaseline gauze, the ultrasound-guided implantation of needle yielded a smaller wound for drainage, more accurate position, adjusted the position and depth of the needle in a timely manner, guaranteed the success of drainage, facilitated subsequent irrigation, and reduced the pain during dressing changes. Intracavity irrigation once daily is able to discharge the ischesis within the necrotic cavity more directly and quickly compared with conventional surface dressing change two to three times per day. Non-traumatic physiotherapy, hot compress, and vacuum suction should be supplemented to consolidate the therapeutic effect. B-ultrasound-guided monitoring, suction, and irrigation play a pivotal role in preventing the recurrence of PCM. The clinical efficacy of this technique has been widely recognized by the clinicians and patients from many provinces and autonomous regions, such as Ningxia, Shanxi, Gansu and Inner Mongolia, etc.

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