A Controlled Trial of a New Treatment for Galactocele

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Abstract

Background : Needle aspiration, followed by excision should it recur, is the standard method of treating galactocele. Villagers in Northeast Thailand traditionally treat galactocele by probing the obstructed duct with double strands of pleated human hair. The aim of the study was to mimic this method in order to scientifically assess its effectiveness.

Patients and Method : Sixteen patients were consecutively enrolled between 1995 and 2001. They elected either standard needle aspiration (Group A) or treatment by 6-0 nylon probing (Group B). The results were compared using the Fisher's exact and Mann-Whitney tests at p-value < 0.05.

Results : The two groups were similar regarding the children's age, first para, mass size, and duration of symptoms, but patients in the aspiration group were considerably younger than the nylon probing group. Both methods reduced the symptoms completely. Pain from treatment was reported by all patients in the aspiration method while there were none in the nylon probing method ($p < 0.001$). The aspiration method took 14.8 minutes less time than the nylon probing method ($p < 0.001$). Recurrence was found in 2 out of 5 patients in the aspiration method, whereas there was none in the 11 patients with the nylon probing method (difference = 40%; 95% CI: -3% to 83%; $p = 0.083$).

Conclusions : The new treatment of galactocele by nylon probing took longer than aspiration but removed the protein plug that caused obstruction of the duct without pain and had a tendency to reduce the recurrence rate.

Key word : Galactocele, Lactational Breast Mass, Probing Method

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Galactocele is caused by obstruction of lactiferous duct. The contents are milk and desquamated epithelial cells[1-5]. It usually occurs in lactating woman[5-9] and is uncommon in male infants[10-15] and nonlactating individuals[16,17]. The symptoms are a breast mass and pain[1-9]. Without treatment, secondary infection may develop such as mastitis or a breast abscess[18].

Aspiration is the recommended method of treatment[1-9,18-20] and excision of the obstructed duct should recurrence occur[18,20].

In rural areas of northeast Thailand, villagers use an easy method with human hair, folded and twisted into a double strand to probe the obstructed duct. The objective of the present study was to assess the efficacy of the modified method using sterile nylon 6-0 instead of hair, and compare the new method with the recommended one.

MATERIAL AND METHOD

Patients

The present study was approved by the Institutional Review Board of Khon Kaen Medical Center. All lactating woman with painful breast lumps who came to private clinics at Khon Kaen Province of Thailand between January 1995 and December 2001 were recruited. The authors excluded patients who had had a breast mass before pregnancy, a breast mass with inflammatory signs, body temperature $\geq 38^{\circ}C$, purulent discharge from the ductal orifice, failed follow-up every day for 7 days, and had organisms from milk culture for bacteria. Informed consent was obtained from all the patients, who were then allowed to choose, either the aspiration or the nylon probing method.

Interventions

For the aspiration method, The authors cleaned the skin with 70 per cent alcohol then aspirated the lump with a 20 G needle with a 20 ml sterile syringe. The lump was squeezed in all directions until the milk content was emptied. A dry gauze dressing was put over the aspiration site.

For the 6-0 nylon probing method, the obstructed duct was first identified. The obstructed duct was characterized by dilation, a white-yellow plug attached on the orifice. The lump was usually related with the anatomical position of the obstructed duct. When the breast was squeezed, there was milk from all ducts except the obstructed duct. Secondly, the plug was softened by warming the breast in warm water ($35^{\circ}C$-$40^{\circ}C$) for 10 minutes. Thirdly, the plug was removed by probing the obstructed duct with nylon 6-0 that had been folded and twisted to a double strand. Then the strand was inserted into the obstructed duct and withdrawn. The plug would thus be attached to the rough surface of the strand. The procedure was repeated until the milk in the galactocele was ejected forcefully. Finally, the galactocele was emptied by squeezing or pumping the breast, particularly at the obstructed lobe. This was done until the lump disappeared.

Outcome and outcome measurements

Statistical methods

The characteristics of patients were summarized by using mean and standard deviation (SD) for continuous variables and proportions for categorical variables. The Mann Whitney test and Fisher's exact test were used to test the difference between the two groups for continuous and categorical outcomes respectively. The differences and their 95 per cent confidence intervals were also estimated. All statistical tests were two-sided using a probability of 0.05 as the significant level. STATA (StatCorp, College Station, TX) was used for all statistical analysis.

RESULTS

A total of 17 lactating woman were recruited. One case with a breast mass before pregnancy was excluded. From 16 study patients, 5 were in the aspiration group and 11 were in the nylon probing group. All selected baseline characteristics of the patients such as their children's age, first para, mass size, and duration of symptoms were similar in both groups (Table 1). However, patients in the aspiration group were considerably younger than the nylon probing group.

Both methods reduced the symptoms completely (Table 2). Pain from treatment was reported by all patients in the aspiration method while there were none in the nylon probing method ($p < 0.001$). The aspiration method took 14.8 minutes less time than the nylon probing method ($p < 0.001$). Recurrence was found in 2 out of 5 patients in the aspiration method, whereas there were none of the 11 patients in the nylon probing method (difference = 40%; 95% CI: -3% to 83%; $p = 0.083$).

DISCUSSION

In the West, galactocele represents about 2.4 per cent of breast diseases in reproductive females

Table 1. Selected baseline characteristics.

Characteristics	Aspiration	Nylon probing
Number (n)	5	11
Mean ± SD of maternal age (years)	25.4 ± 10.16	29.09 ± 1.36
Mean ± SD of infant age (months)	4 ± 2.35	5.64 ± 3.20
Number (%) of nursing the first para	4 (80%)	9 (82%)
Mean ± SD duration of symptoms before treatment (days)	2 ± 0.74	1.91 ± 0.70
Mean ± SD of mass size (cm)	1.5 ± 0.41	1.3 ± 0.45

Table 2. Treatments and outcomes presented as number (%) unless otherwise indicated.

	Aspiration method	Nylon probing	Difference (95% CI)	P-value
Number of subjects	5	11		
Mean ± SD duration of treatment (minutes)	4.8 ± 1.1	19.5 ± 4.7	-14.8 (-19.4 to -10.1)	< 0.001*
Pain caused by the treatment	5 (100%)	0 (0%)	100%	< 0.001†
Cured	5 (100%)	11 (100%)	0%	-
Recurrence	2 (40%)	0 (0%)	40% (-3% to 83%)	0.083†

* Mann Whitney test
† Fisher's exact test

(21). There are no incidence reports for Thailand. Our experience in Srinagarind Hospital, we found few cases; possibly because Northeast Thais treat themselves using the hair probing method. The authors had the largest number of reported cases(21-24) perhaps because free treatment is offered should galactocele occur.

The authors found galactocele in 13 women who were nursing their first para and 3 nursing their second. Two of the three had not breastfed their first babies suggesting an incidence in first para or first lactation was more common. The incidence was high in the first 4 to 5 months after delivery, particularly when the mother went back to work after her 3-month maternity leave, and breastfeeding decreased.

Unlike other studies(21,25), only 3 of 16 cases in the present study had associated use of exogenous hormones (oral contraceptive pills). All the patients were healthy lactating women so the authors concluded the galactocele was due to a mechanical obstruction rather than exogenous hormones.

In the present study, the authors could not conduct a randomized control because the patients chose the treatment, notwithstanding, the demographic data of both groups were not significantly different according to the Fisher-exact and Mann-Whitney rank sum tests.

From the authors' experience, recurrence usually occurred within 7 days, so those who could not attend 7 days of follow-up were excluded. Follow-up by telephone after one month was done to make sure that the galactocele had not recurred. This included two patients who were treated by probing after recurrence by needle aspiration.

A wide variation of ultrasonographic presentations mimic other lesions of the breast, both benign and malignant(23,26-31). Mammography during pregnancy and lactation has poor sensitivity because of the increased density(27). So ultrasonography and mammography have little use in the diagnosis of galactocele during lactation. Although the authors did not aspirate the galactocele for definite diagnosis in all cases, a breast lump with pain during lactation and an obstructed duct, with milk ejection after probing, made possible the differentiation of galactocele, infected galactocele or a breast abscess. The authors cultured the ejected milk in all cases and found no bacterial growth; infected galactocele and breast abscess could, therefore, be excluded in all cases. The authors, therefore, present a new diag-

nostic method and an effective treatment for lactational galactocele using the nylon probing method; the procedure may be regarded at once diagnostic and therapeutic.

The authors modified the probing method by immersing the breast in warm water, thereby, softening the plug and easing insertion of the nylon strand since plugs in for a long time make insertion of the nylon more difficult.

When comparing the two methods, it was found that both reduced symptoms but the nylon probing took about 15 minutes longer to accomplish ($p < 0.001$). Although no statistical difference in recurrence ($p = 0.083$) was found, the needle aspiration method had a tendency to recur more often than the probing method if the sample size is larger. Further study, with a larger sample population, is required.

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การทดลองแบบมีกลุ่มควบคุมในการรักษากาแลคโตซีลวิธีใหม่

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วิธีมาตรฐานในการรักษากาแลคโตซีลคือ การใช้เข็มเจาะดูดออก หากเป็นซ้ำจะทำการผ่าตัดนำท่อน้ำนมที่ถูกอุดตันออกไป ซึ่งเป็นวิธีการรักษาที่ค่อนข้างรุนแรง สำหรับชาวไทยอีสานพื้นเมืองรู้จักกาแลคโตซีลในนาม "นมหลงรู" และมีวิธีรักษาตัวเองที่ได้ผลดี โดยการนำเส้นผมมาพับทบกันแล้วบิดเป็นเกลียวแยงผ่านรูเปิดท่อน้ำนมที่ถูกอุดตัน

การวิจัยครั้งนี้จึงได้มีการนำวิธีดังกล่าวมาประยุกต์โดยใช้ไนล่อน ขนาด 6-0 พับทบกันแล้วบิดเป็นเกลียว แยงผ่านรูเปิดท่อน้ำนมที่อุดตันด้วยวิธีปลอดเชื้อ ซึ่งจะเรียกวิธีนี้ว่าวิธีใหม่ เปรียบเทียบการรักษากับวิธีมาตรฐาน ในหญิงให้นมบุตรที่มาด้วยก้อนและเจ็บที่เต้านมจำนวน 16 ราย ผู้ป่วย 4 รายเลือกรักษาด้วยวิธีมาตรฐาน 11 รายเลือกวิธีใหม่ โดยผลการรักษาที่ได้นำมาเปรียบเทียบกันโดยใช้ Fisher's exact test และ Mann Whitney test โดยกำหนดนัยสำคัญค่า p ที่น้อยกว่า 0.05

ผลการศึกษาพบว่าทั้งสองกลุ่มไม่มีความแตกต่างในเรื่องอายุบุตรที่กำลังให้นม ขนาดของก้อน, เป็นการให้นมบุตรคนแรก ระยะเวลาของการเป็นโรคก่อนมาพบแพทย์ แต่อายุของผู้ป่วยในกลุ่มที่รักษาด้วยวิธีมาตรฐานน้อยกว่า ทั้งสองวิธีสามารถลดอาการปวด และขนาดของก้อนได้อย่างสมบูรณ์ ในกลุ่มที่รักษาด้วยวิธีมาตรฐานพบว่าเจ็บจากการรักษาทุกราย ในขณะที่การใช้วิธีใหม่ไม่มีใครเจ็บจากการรักษาเลย ($p < 0.001$) วิธีมาตรฐานใช้เวลาน้อยกว่าวิธีใหม่ 14.8 นาที ($p > 0.001$) การกลับเป็นใหม่โดยวิธีมาตรฐาน 2 ใน 5 ราย ในขณะที่วิธีใหม่ไม่มีผู้กลับเป็นใหม่เลย (difference = 40%, 95% CI: -3% ถึง 83%)

การรักษาด้วยวิธีใหม่แม้ว่าจะใช้เวลานานกว่า แต่สามารถเอาก้อนโปรตีนที่อุดตันท่อน้ำนมซึ่งเป็นสาเหตุของกาแลคโตซีลได้โดยไม่เจ็บปวด และมีแนวโน้มจะลดอัตราการกลับเป็นซ้ำได้

คำสำคัญ : กาแลคโตซีล, ก้อนที่เต้านมระยะให้นมบุตร, วิธีการแยง

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