Original Article

Clinical effectiveness of microporous polysaccharide hemospheres in mastectomy for patients with breast cancer

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Background: Microporous polysaccharide hemospheres (MPH) are hydrophilic particles administered to reduce the incidence of seroma after mastectomy, but their clinical effectiveness remains controversial. Because a previous randomized, controlled study in a small cohort could not demonstrate the effectiveness of MPH in breast surgery, we evaluated their effectiveness in surgery for breast cancer in a larger cohort.

Methods: Medical records of 352 patients who underwent total mastectomy for breast cancer were retrospectively reviewed. Clinical data were compared between 126 patients who received MPH during surgery (MPH group) and 226 who did not (control group) according to surgical procedures. Patients were significantly older in the MPH group than in the control group because of selection bias, but other factors, such as body mass index and number of dissected lymph nodes, did not differ between groups.

Results: When analyzed by use of axillary manipulation, the drain placement period and drainage volume were significantly less in the MPH group than in the control group for patients with mastectomy and sentinel lymph node biopsy. Only drainage volume was significantly less in the MPH group for patients with mastectomy and axillary lymph node dissection. The frequency of total postoperative complications, such as seroma requiring puncture, did not differ between groups.

Conclusions: Use of MPH may decrease the postoperative drainage volume and drain placement period in mastectomy for patients with breast cancer.

Keywords: Microporous polysaccharide hemospheres (MPH); breast cancer surgery; drain placement period; drainage volume

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Introduction

Microporous polysaccharide hemospheres (MPH) are hydrophilic polysaccharide particles with a diameter of 30–100 μm that are made from 100% purified potato starch and are currently used as absorbable hemostatic agents. MPH particles extract fluid from the blood, swell to form a gelatinous matrix to concentrate serum proteins, platelets, albumin, thrombin and fibrinogen, and create a scaffold for the formation of a fibrin clot (1,2). Egeli and colleagues reported that MPH could significantly reduce the incidence of seroma after mastectomy and axillary dissection in rats (3). However, the clinical effectiveness of MPH remains controversial. Several randomized, controlled studies could not demonstrate the effectiveness of MPH in patients who underwent breast, thyroid and endoscopic sinus surgery (4-6). In contrast, the effectiveness of MPH in cardiothoracic surgery and total knee arthroplasty has been shown in several retrospective analyses (7,8). In this retrospective study, we evaluated the effectiveness of MPH in breast cancer surgery. We present this article in accordance with the STROBE reporting checklist (available at https://gs.amegroups.com/article/view/10.21037/gs-23-297/rc).

Methods

Patients

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics board of Kagoshima University Hospital (No. 220041-Epidemiology). Individual consent for this retrospective analysis was waived. Medical records of 352 consecutive patients who underwent total mastectomy for breast cancer at Kagoshima University Hospital were retrospectively reviewed. Between December 2020 and April 2023, we used MPH for all patients who underwent mastectomy with or without axillary dissection (126 patients, MPH group). As a control, we compared the clinical data of 226 patients who underwent mastectomy between January 2015 and November 2020, when we did not use MPH. Patients over 90 years of age and those who underwent breast reconstruction or skin transplantation were excluded. Surgical procedures were total mastectomy, mastectomy with sentinel lymph node biopsy (SLNB) and mastectomy with axillary lymph node dissection (ALND). Ultrasonic or microwave dissectors were used for ALND, depending on the surgeon's preference, and two drainage tubes were placed for all patients. One gram of MPH (Arista™ AH, C. R. Bard, Inc. Davol, Warwick, RI, USA) was applied to the chest wall and axillary region before wound closure. The drainage tubes were removed when the daily drainage output was below 50 mL per 24 hours, or 14 days after surgery. The collected clinical data were age, height, body weight and body mass index (BMI), and outcomes such as drain placement period duration, drainage output and postoperative complications. Postoperative hemorrhage, seroma formation, wound infection and skin necrosis were recognized as postoperative complications. Postoperative hemorrhage was defined as requiring additional compression after surgery. No patient in our cohort required additional surgery for hemorrhage. Seroma was defined as requiring puncture after drain removal. Wound infection was defined as requiring drainage and/or antibiotic administration, and skin necrosis was defined as wound dehiscence and/or crust formation requiring debridement.

Statistical analysis

Differences between groups were evaluated with the Wilcoxon test for continuous variables and the Pearson Chi-square test for categorical variables. Statistical analysis was performed using JMP Pro, version 16.1.0 for Mac OS (SAS Institute Japan Ltd., Tokyo, Japan). P values <0.05 were considered statistically significant.

Results

Patient characteristics are shown in *Table 1*. Patients in

Highlight box

Key findings

- Use of microporous polysaccharide hemospheres (MPH) decreased the postoperative drainage volume and drain placement period in mastectomy for patients with breast cancer.

What is known and what is new?

- A previous randomized, controlled study could not demonstrate the effectiveness of MPH in breast surgery, but it was performed in a small cohort (N=50).
- Although our study was retrospective, we analyzed a larger number of patients and showed the effectiveness of MPH in mastectomy for patients with breast cancer.

What is the implication, and what should change now?

- For improving postoperative quality of life, use of MPH could be recommended in mastectomy for patients with breast cancer.

Table 1 Patient characteristics

Characteristics	Control (n=226)	MPH (n=126)	P value
Age (years)	64.4 [29–89]	68.9 [36–89]	0.0021
Sex, female/male	220/6	123/3	0.88
Height (cm)	153.1 [134–178]	152.4 [134–170]	0.31
Body weight (kg)	56.1 [32–93]	54.1 [35–80]	0.1
BMI (kg/m^2)	24.0 [13.5–44.2]	23.2 [16.1–34.6]	0.18
Operation method, SLNB/ALND	132/94	101/25	<0.0001

Data are presented as mean [range] or number. BMI, body mass index; SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection; MPH, microporous polysaccharide hemospheres.

Table 2 Patient characteristics and outcomes in patients without axillary dissection

Characteristics	Control (n=132)	MPH (n=101)	P value
Age (years)	66.7 [35–89]	69.2 [36–89]	0.14
Height (cm)	152 [134–170]	152 [139–170]	>0.99
Body weight (kg)	56.6 [32–93]	54.3 [35–80]	0.11
BMI (kg/m^2)	24.4 [13.5–44.2]	23.3 [16.1–34.6]	0.08
Intraoperative blood loss (mL)	26 [0–235]	29 [0–128]	0.43
Number of dissected lymph nodes	2.4 [0–15]	2.1 [0–11]	0.3
Drain placement period (days)	5.8 [3–14]	4.7 [3–13]	0.0003
Total drainage volume (mL)	321 [27–1,761]	254 [68–1,010]	0.03
Postoperative complications, present/absent/NA*	31/81/20	21/67/13	0.54

Data are presented as mean [range] or number. *, not available because some patients were transferred to other hospitals after surgery. BMI, body mass index; NA, not available; MPH, microporous polysaccharide hemospheres.

the MPH group were significantly older (P=0.0021), and received axillary dissection significantly less frequently (P<0.0001) than those in the control group (*Table 1*). For analysis of the clinical effectiveness of MPH, we analyzed patients with SLNB and ALND separately. For patients with SLNB, there were no significant differences in background characteristics, such as age, height, body weight, BMI, intraoperative blood loss and number of dissected lymph nodes. The drain placement period was significantly shorter and the total drainage volume was significantly smaller in the MPH group compared with the control group (*Table 2*). Analysis of the variations in the daily amount of drainage found that a significant decrease in drainage volume occurred on postoperative days 2, 3 and 4 in the MPH group compared with the control group (*Figure 1*). For patients with ALND, age was significantly higher in the MPH group than in the control group. There was no significant difference between groups in patient background characteristics, such as height, body weight, BMI, intraoperative blood loss and number of dissected lymph nodes. The drain placement period was significantly shorter in the MPH group than in the control group, but the total drainage volume did not differ between groups (*Table 3*). Analysis of the variations in the daily amount of drainage found that a significant decrease in drainage volume occurred on postoperative days 2, 3, 4 and 5 in the MPH group compared with the control group (*Figure 2*). There was no difference in the frequency of total postoperative complications between the MPH group and the control group, regardless of surgical procedure. When types of complications were analyzed, skin necrosis was significantly less frequent in the MPH group, but the incidence of other

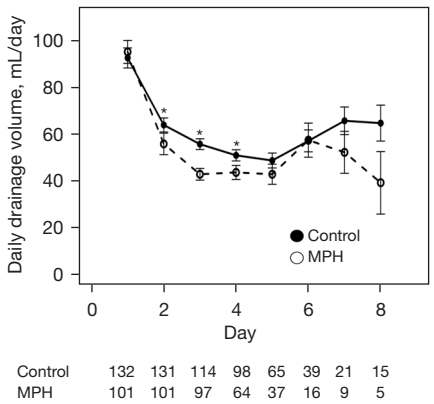

Figure 1 Daily variations in drainage volume in patients without axillary dissection. Daily drainage amounts in the control group and the MPH group. Error bars show standard deviation and asterisks show significant differences between groups. The numbers at the bottom represent the number of patients who had a drain placed on each day. MPH, microporous polysaccharide hemospheres.

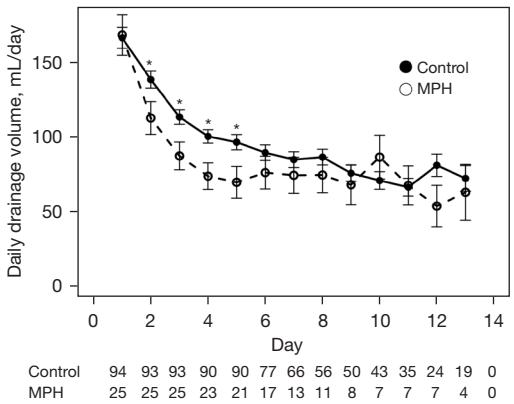

Figure 2 Daily variations in drainage volume in patients with axillary dissection. Daily drainage amounts in the control group and the MPH group. Error bars show standard deviation and asterisks show significant difference between groups. The numbers at the bottom represent the number of patients who had a drain placed on each day. MPH, microporous polysaccharide hemospheres.

Table 3 Patient characteristics and outcomes in patients with axillary dissection

Characteristics	Control (n=94)	MPH (n=25)	P value
Age (years)	61 [29–87]	68 [38–89]	0.03
Height (cm)	154 [134–178]	152 [134–166]	0.2
Body weight (kg)	55 [36–88]	53 [38–74]	0.38
BMI (kg/m^2)	23.3 [15.6–34.2]	23.0 [17.3–28.7]	0.75
Intraoperative blood loss (mL)	42 [0–244]	55 [0–176]	0.17
Number of dissected lymph nodes	17 [3–41]	14 [8–22]	0.12
Drain placement period (days)	9.8 [4–14]	8.3 [3–14]	0.038
Total drainage volume (mL)	925 [168–2,720]	709 [156–1,874]	0.064
Post operative complications, present/absent/NA*	39/43/12	8/15/2	0.28

Data are presented as mean [range] or number. *, not available because some patients were transferred to other hospitals after surgery. BMI, body mass index; NA, not available; MPH, microporous polysaccharide hemospheres.

complications did not differ between groups (*Table 4*).

Discussion

MPH is theoretically expected to reduce hemorrhage and serous exudate (1,3), while its clinical effectiveness remains controversial. Several randomized, controlled studies in various types of surgery, including breast surgery, could not establish the effectiveness of MPH (4-6), while other retrospective studies showed the effectiveness of MPH in cardiothoracic surgery and total knee arthroplasty (7,8). One reason for such a discrepancy may be the small study populations that were analyzed. Suarez-Kelly and colleagues could not show the effectiveness of MPH in mastectomy, but that study included only 50 patients who underwent various axillary manipulation techniques (4). In the current study, we analyzed a much larger population (352 patients) and showed the effectiveness of MPH in breast cancer

Table 4 Postoperative complications

Variables	SLNB			ALND		
	Control (n=132)	MPH (n=101)	P value	Control (n=94)	MPH (n=25)	P value
Any complications, present/absent/NA (n)	31/81/20	21/67/13	0.54	39/43/12	8/15/2	0.28
Hemorrhage, present/absent (n)	1/131	0/101	0.38	2/92	0/25	0.46
Infection, present/absent (n)	2/130	0/101	0.21	6/88	0/25	0.2
Skin necrosis, present/absent (n)	6/126	0/101	0.03	8/86	1/24	0.004
Seroma, present/absent/NA (n)	28/84/20	17/81/3	0.18	32/50/12	7/16/2	0.45
Number of aspiration for seroma, mean	1.9	3	0.07	2.8	2.3	0.56
Total amount of seroma (mL), mean	145	221	0.33	292	297	0.98

NA, not available; SLNB, sentinel lymph node biopsy; MPH, microporous polysaccharide hemospheres; ALND, axillary lymph node dissection.

surgery.

In our cohort, the incidence of postoperative complications was 28% (100 of 352 cases). Previous studies reported postoperative seroma incidence ranging from 0 to 35% in patients who underwent total mastectomy (4,9-11). Our outcomes are comparable with the previous data.

When we divided the patient population into two subgroups by surgical procedure (with and without ALND), MPH significantly decreased the drain placement period and the daily drainage volume in both subgroups, and the total drainage volume in the SLNB subgroup (*Tables 2*,*3*, *Figures 1*,*2*). In both the ALND and SLNB subgroups, the daily drainage volume in the MPH group reached a plateau and overlapped with that of the control group. This was attributed to the dropout of patients whose drainage output was small and whose tubes were removed. There was no difference between the MPH group and the control group in postoperative complications, except for skin necrosis. It is unclear why skin necrosis was less frequent in the MPH group. However, since the incidence of complications other than seroma was low, future studies with larger numbers of patients are needed.

Many studies have shown no effect of hemostatic agents, including MPH, fibrin glue, oxidized regenerated cellulose, polysaccharide hemostatic agents and local sclerosing agents, in breast cancer surgery (4,12-18). However, a systematic review concluded that the use of fibrin glue reduced the incidence of seroma, the postoperative drainage volume, and the duration of drainage (19). Thus, the efficacy of hemostatic agents remains controversial.

One disadvantage of using MPH is cost. One gram of MPH costs about $85 in Japan. The time required for use of MPH in surgery is less than one minute. Because the substance is derived from starch, there is no risk of allergy, and no other complications were observed in our experience.

This study has some limitations. First, it was a retrospective study, and some selection biases existed between groups. Age was higher in the MPH group than in the control group, especially in the ALND subgroup. Previous studies reported several risk factors that could contribute to drainage volume and seroma formation. Burak and colleagues reported risk factors for seroma formation after mastectomy and ALND as increased age, patient weight and other factors (20). In this study, the MPH group with elderly patients had smaller drainage volumes and a decreased incidence of seroma suggesting that the effectiveness of MPH was not affected by the selection bias of age. In addition, differences in surgeon experience and surgical equipment existed, because the timing of surgery was different in groups with and without MPH use. The detailed differences were not examined in this study. Second, the impact of MPH on number of hospitalization days was not examined, because it could be influenced by patient social background characteristics.

As a result, we showed that the use of MPH could decrease the drainage output and the number of drainage days. A disadvantage of using MPH is the increased cost of the surgical procedure, but the total cost effectiveness should be revealed with further study. For evaluation of the definitive clinical effectiveness of MPH in breast cancer surgery, a clinical trial with an appropriate number of cases

is needed.

Conclusions

Use of MPH in mastectomy for patients with breast cancer was associated with decreased drainage output and fewer drainage days.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://gs.amegroups.com/article/view/10.21037/gs-23-297/rc

Data Sharing Statement: Available at https://gs.amegroups.com/article/view/10.21037/gs-23-297/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://gs.amegroups.com/article/view/10.21037/gs-23-297/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics board of Kagoshima University Hospital (No. 220041-Epidemiology). Individual consent for this retrospective analysis was waived.

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