Original Study

Effect of Microporous Polysaccharide Particles in Patients Undergoing Mastectomy

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Abstract

Microporous polysaccharide particles (MPP), a hemostatic agent, were evaluated for post-operative outcomes. 190 patients were retrospectively reviewed. No difference was noted between those treated with and without MPP with regards to infection, seroma, or hematoma. Lymphovenous anastomosis (LVA) patients were more at risk of seroma and less likely to receive MPP. Consider utilizing MPP in this LVA population.

Background: Microporous polysaccharide particles (MPP, proprietary name "Arista AH"), derived from purified plant starch, are used to augment hemostasis at surgery. The effect of MPP regarding short-term complications after mastectomy remains an area of ongoing investigation. **Patients and Methods:** A single-institution, retrospective chart review of patients undergoing unilateral mastectomy without reconstruction from January 2019 to 2021 was performed. Primary endpoints included antibiotic prescription, seroma or abscess drainage, readmission, wound dehiscence, and time to drain removal within 30 days of initial surgery. Wilcoxon rank sum test or Student *t* test was used for group comparisons for continuous variables; Chi-square test or Fisher exact test was used to evaluate the associations among categorical variables. **Results:** One hundred ninety patients were included; 119 received MPP and 71 did not. There was no difference in antibiotic prescription, infection drainage, hematoma, readmission, dehiscence, or time to drain removal with regards to MPP use. MPP treated patients were older (65.8 years vs. 59.1, $P < .001$) and had lower albumin levels (4.1 g/dL vs. 4.3, $P = .025$). Patients who underwent abscess drainage had higher body mass index (mean 36.1 vs. 30.1 $P = .036$). Patients requiring seroma drainage were more likely to be diabetic (12.8% vs. 4%, $P = .035$) and to have been treated with lymphovenous anastomosis (LVA, 15.6% vs. 3.8%, $P = .009$). Patients who had LVA were significantly less likely to receive MPP when compared to other groups (3.1% vs. 74.7% $P < .001$). **Conclusion:** Consider utilizing MPP in patients at higher risk of seroma, such as those undergoing axillary surgery including LVA.

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Introduction

Mastectomy with and without axillary surgery is one of the most common breast procedures utilized in the treatment of breast cancer, with seroma, hematoma, and infection remaining among the most frequent complications.[1] These complications can delay adjuvant treatment such as chemotherapy leading to poorer outcomes for patients.[2] Mastectomy patients who face post-operative complications are also negatively impacted emotionally.[3,4,5] For these reasons, preventing complications such as hematoma remains an area of interest to surgeons. Hemostatic agents are one potential tool to reduce hematoma rates, and by extension, reduce the risk of a negative patient experience and subsequent delays in care.

Microporous polysaccharide particles (MPP) are used to augment hemostasis at surgery. MPP is composed of purified plant starch. The mechanism of action of MPP relies upon the hydrophilic nature of these microporous particles. Each particle functions as a sieve in which tissue fluid is absorbed and platelets are concentrated, along with red blood cells, and blood proteins on the particle surface.[6] The effect of MPP and patient factors on short-term complications after mastectomy remains under investigation.

An unpublished randomized clinical trial described in the Food and Drug Administration approval process included 288 patients within 9 centers in which MPP was compared to a gelatin sponge with or without thrombin in orthopedic, general, and cardiac surgeries. Seventy two of the 288 patients were general surgery

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patients treated with MPP. Infection and seroma were noted in less than 5% of patients receiving MPP in this trial. Preclinical testing in this report indicates that MPP is absorbed within 24 to 48 hours.[7] However, complication rates for infection, hematoma, and seroma were not specifically identified for breast surgical oncology patients with this research.

Prior retrospective evaluation of patients undergoing mastectomy with other hemostatic agents, specifically fibrin sealant or a combination powder including porcine-derived collagen, bovine-derived chondroitin sulfate, thrombin, and fibrinogen demonstrated significantly decreased incidence rates of seroma and hematoma, and decreased time until drain removal.[8] There is conflicting evidence of the effect of MPP on seroma rate and time to drain removal in mastectomy patients. A study of seroma rate in rats after unilateral mastectomy and axillary dissection with and without MPP demonstrated lower volumes of seroma formation after MPP use on post-operative day 10.[9] A prospective randomized clinical trial evaluating MPP use in patients undergoing mastectomy evaluated 42 patients prior to early termination related to funding. This trial did not demonstrate a significant reduction in post-operative drainage after use of MPP. Body mass index (BMI) 30 or higher was noted to be a risk factor for increased drain output.[10] Prior evaluation of patients undergoing axillary sentinel lymph node biopsy (SLNB) for melanoma with and without MPP use also demonstrated decreased lymphocele formation. This was performed in a prospective matched control trial, and it was noted that the reduction in lymphoceles was greater for axillary than groin sites.[11]

Although seroma formation has been investigated after use of MPP and various other hemostatic agents, we sought to further explore additional complications including infection, dehiscence, and time to drain removal in our mastectomy patients without reconstruction given its ubiquity in our practice. At our institution, some patients undergo axillary lymphatic to venous anastomosis (LVA), also known as lymphovenous bypass, at the time of axillary dissection; these patients were included in our analysis. The type of axillary surgery at the time of mastectomy will also be evaluated in relation to these outcomes.

Patients and Methods

A single-institution, retrospective chart review of clinicopathological characteristics of patients undergoing unilateral mastectomy without reconstruction from January 2019 to 2021 was performed. No patient received an axillary counter-incision at the time of mastectomy. In all cases, MPP was distributed per the manufacturer's directions over the entire contiguous surgical field of chest wall and axilla after all specimens were removed. There was no specific protocol for surgeon drain removal or use of 2 drains. All drains were 15 French Blake drains and placed to encompass the entire breast and axillary surgical field.

Clinicopathological characteristics included in our analysis included age, race, surgeon, axillary surgery performed, whether LVA was performed, BMI, weight of MPP used, tissue diagnosis, neoadjuvant treatment, menopausal status, use of antiplatelet or anticoagulation therapy, prior diagnosis of diabetes, tobacco use within thirty days of surgery, albumin measurement (if available within 90 days preoperatively), history of ipsilateral breast surgery with particular attention to surgery within the past year, and prior ipsilateral breast irradiation. Patients undergoing additional concurrent surgery other than port removal were excluded. Six breast surgical oncologists were included in the study, and one plastic surgeon performed LVA in conjunction with these surgical oncologists. All patients had a diagnosed malignancy in the operative breast, including DCIS. Patients were excluded if they were male, pregnant, or had a pre-operatively diagnosed infection that required antibiotics within the 30-day post-operative period. Male patients were excluded to limit factors related to body habitus and muscle to breast ratio. Patients who underwent surgery 30 days before or after their mastectomy were excluded, except when related to complications such as hematoma, wound drainage, or wound debridement. Patients who had an incision wound vacuum device placed or whose drain was inadvertently removed prior to surgeon recommendation were excluded. Dehiscence was determined by physician documentation of superficial wound changes. A patient with prior intraoperative radiation within 2 months of mastectomy was also excluded. No patients required re-operation for seroma; the only seroma management that was therefore recorded was needle drainage outside of the operating room.

Primary endpoints included antibiotic prescription, hematoma requiring reoperation, seroma or abscess drainage, readmission, wound dehiscence, and time to drain removal within 30 days of initial surgery. Wilcoxon rank sum test or Student *t* test was used for group comparisons for continuous variables. Chi-square test or Fisher exact test was used to evaluate the associations among categorical variables. *P*-values are 2-sided and a *P*-value less than .05 was considered to be statistically significant.

Results

A total of 190 patients were included in our retrospective review of medical and pharmacy records from January 2019 to January 2021. MPP had not been used frequently at the institution prior to that period.

Patient Characteristics

MPP was used in 62.6% (N = 119) of patients, with a mean of 2.13 g per mastectomy. There was significant variation of MPP use between surgeons, with a range of one surgeon using MPP in 27.3% of cases to another using the product in 100% of cases ($P < .001$). The mean age of patients included was 63.3 years (range 21.7- 95.2 years) and mean BMI was 30.2 (range 16.7- 66.3). MPP-treated patients were older (65.8 years vs. 59.1, $P < .001$).

Patients receiving neoadjuvant chemotherapy were more likely to receive MPP than patients who did not receive these therapies (53.3% vs. 68.7%, $P = .032$). Of patients who developed seroma requiring drainage, 54.5% had received neoadjuvant chemotherapy. Of these patients, none received MPP.

Postmenopausal women were more likely to receive MPP (70.7% vs. 29.3%) and premenopausal women were less likely to receive MPP (32.5% vs. 67.5%, $P < .001$). Patients treated with MPP had lower albumin levels (mean 4.09 with MPP vs. 4.25 without MPP, $P = .025$).

Patient characteristics are further described in Table 1.

Table 1 Patient Characteristics

Variable		All Patients	Patients Treated With MPP	Patients Treated Without MPP	*P*-value
Age (y, mean, range)		63.3 (21.7-95.2)	65.8	59.1	**<.001**
Body Mass Index (mean, range)		30.2 (16.7-66.3)	30.3	30.2	.394
		Percentage (Total N = 190)	% (N)	% (N)	
Albumin Level (g/dL, mean)			4.1	4.3	**.025**
Race					.549
	White	75.3% (143)	63.6% (91)	36.4% (52)	
	Black	12.1% (23)	69.6% (16)	30.4% (7)	
	Hispanic	5.8% (11)	54.5% (6)	45.5% (5)	
	Asian	4.2% (8)	37.5% (3)	62.5% (5)	
	Multiracial	2.6% (5)	60% (3)	40% (2)	
Neoadjuvant chemotherapy					**.032**
	No	60.5% (115)	68.7% (79)	31.3% (36)	
	Yes	39.5% (75)	53.3% (40)	46.7% (35)	
Menopausal status					**<.001**
	Premenopausal	21.1% (40)	32.5% (13)	67.5% (27)	
	Postmenopausal	78.9% (150)	70.7% (106)	29.3% (44)	
Chronic anticoagulation or antiplatelet use					**.040**
	No	71.6% (136)	58.1% (79)	41.9% (57)	
	Yes	28.4% (54)	74.1% (40)	25.9% (14)	
Diabetes					.559
	No	79.5% (151)	61.6% (93)	38.4% (58)	
	Yes	20.5% (39)	66.7% (26)	33.3% (13)	
Tobacco use					.991
	No	91.6% (174)	62.6% (109)	37.4% (65)	
	Yes	8.4% (16)	62.5% (10)	37.5% (6)	
Prior ipsilateral breast surgery					.462
	No	84.2% (160)	63.8% (102)	36.3% (58)	
	Yes	15.8% (30)	56.7% (17)	43.3% (13)	
Prior ipsilateral breast radiation					1.000
	No	95.8% (182)	62.6% (114)	37.4% (68)	
	Yes	4.2% (8)	62.5% (5)	37.5% (3)	
Surgery type					
	Total mastectomy	6.8% (13)	69.2% (9)	30.8% (4)	.770
	Total mastectomy with sentinel lymph node biopsy	52.1% (99)	71.7% (71)	28.3% (28)	**.007**
	Modified radical mastectomy	24.2% (46)	82.6% (38)	17.4% (8)	**.001**
	Modified radical mastectomy with lymphovenous anastomosis	16.8% (32)	3.1% (1)	96.9% (31)	**<.001**

Abbreviations: BMI = body mass index; LVA = lymphovenous anastomosis; MRM = modified radical mastectomy; SLNB = axillary sentinel lymph node biopsy; TM = total mastectomy.
Values with p-value <0.05 were bolded.

Table 2 Overall Complication Rates

Complication Within 30 Days of Initial Surgery	Percentage (N = Total 190)	Mean (Standard Deviation)
Antibiotic prescription	9.5% (N = 18)	
Hematoma	3.2% (N = 6)	
Infection requiring drainage	1.6% (N = 3)	
Seroma drainage	5.8% (N = 11)	
Readmission	1.6% (N = 3)	
Dehiscence	1.6% (N = 3)	
Time to drain removal (d)		15.05 (6.08)

Complication Rates

For all patients, overall complication rates are listed in Table 2. Of note, 9.5% of all patients were prescribed antibiotics, while 1.6% required drainage of infection. 5.8% of patients underwent seroma drainage. 3.2% of patients required operative intervention for hematoma. The mean time to drain removal for all patients was 15.0 days.

When evaluating our data for patient factors, our data indicates that diagnosis, race, neoadjuvant treatment, menopausal status, chronic anticoagulant or antiplatelet use, diabetes, tobacco use, ipsilateral breast surgery, or prior ipsilateral breast radiation treatment, axillary surgery including LVA, or surgeon was not associated with antibiotic prescription, infection drainage, readmission, or dehiscence.

We found that there was no difference in antibiotic prescription, infection drainage, hematoma, readmission, dehiscence, or time to drain removal in patients with or without MPP.

Our results did not indicate a clear trend between seroma formation and MPP use. For example, of patients who had undergone seroma drainage after SLNB, all these patients had received MPP. In contrast, 85.7% of patients who had developed a seroma after axillary lymph node dissection had not been treated with MPP. However, when specifically examining this group further to include only MRM patients with LVA, 0% of patients were treated with MPP.

The LVA procedure itself was associated with seroma development; 15.6% of patients with LVA experienced a seroma compared to 3.8% of patients who did not undergo this surgery ($P = .009$). Additionally, patients requiring seroma drainage were more likely to be diabetic; 12.8% of diabetics required this intervention compared to 4% of those without diabetes ($P = .035$).

Patients that required abscess drainage were noted to have higher BMI compared to those that did not require this treatment (mean BMI 36.1 vs. 30.2 $P = .036$). Patients with dehiscence were also found to have higher average BMI (34.6 vs. 30.2 $P = .003$).

Only chronic anticoagulation or antiplatelet use was associated with increased risk of hematoma (9.3% vs. 0.7% in those who did not use these medications, $P = .008$). Patients receiving these medications were statistically more likely to have received MPP than those who were not on anticoagulation or antiplatelet agents (74.1% vs. 58.1%, $P = .040$). A description of these complications and use of MPP is listed in Table 3.

Discussion

Our results did not demonstrate a difference in various outcomes, including antibiotic prescription, infection drainage, hematoma, readmission, dehiscence, or time to drain removal with use of MPP. Our research emphasizes that MPP does not increase the risk of infection, including infections that require antibiotics to more advanced infections that require drainage. This is consistent with findings from other animal model research and randomized trial findings.[10,12,13]

Prior research from multiple surgical specialties has demonstrated the efficacy of MPP as a hemostatic agent,[14-17] while other studies call this benefit into question.[13-20] Our data does not demonstrate a beneficial effect of MPP use with hematoma rate. Patients on chronic antiplatelet and anticoagulation medications had a higher rate of hematoma (9.3% vs. 0.7%, $P = .008$) in the setting of also being more likely to receive MPP (74.1% vs. 25.9% for those not on these medications, $P = .040$). Thus, we cannot conclude that MPP provided a benefit as a hemostatic agent in this context.

The effect of MPP on seroma development was varied across our patient subset analysis, and there was no clear benefit to MPP use with regards to seroma drainage or time to drain removal. All patients who required seroma drainage after mastectomy with sentinel lymph node biopsy had also received MPP. For these patients, MPP did not appear to protect against seroma formation. In contrast, the majority of LVA patients did not receive MPP, and while this may affect seroma formation, these patients were frequently restricted in additional behaviors, such as the use of post-operative chest compression binders. Compression garments are otherwise routinely used for postoperative mastectomy patients universally across surgeons at this institution. Although our data suggests that patients undergoing LVA have higher seroma rates than those who do not undergo this procedure, the use of MPP in this population requires careful consideration, as the MPP would cause osmotic changes adjacent to this microscopic anastomosis.

Limitations of this study include its retrospective design at a single academic institution. The surgeons involved were not blinded to treatment with MPP and this may have introduced bias. There was likely practice variation between the 6 breast surgical oncologists included. This variation is expected to include decision-making regarding use of MPP, threshold to drain seromas, discretion related to drain removal, and decision-making regarding return to the operating room for complications. Because the operative

Table 3 Complications for Patients Treated With and Without MPP

Complications		Treated With MPP	Treated Without MPP	*P*-value
Antibiotics prescribed within 30 days of initial surgery				
	Age (mean)	65.8	71.3	.282
	BMI (mean)	32.6	30.8	.510
	Albumin level (mean)	4.0	4.2	.551
	Neoadjuvant chemotherapy given No. (%)	5 (83.3%)	1 (16.7%)	.222
	Antiplatelet/anticoagulant use No. (%)	3 (42.9%)	4 (57.1%)	.630
	TM No. (%)	0 (0%)	0 (0%)	NA
	TM + SLNB No. (%)	5 (50%)	5 (50%)	.664
	MRM No. (%)	5 (83.3%)	1 (16.7%)	.152
	MRM + LVA No. (%)	0 (0%)	2 (100%)	.183
Infection requiring drainage within 30 d				
	Age (mean)	65.1	NA	NA
	BMI (mean)	36.1	NA	NA
	Albumin level (mean)	4	NA	NA
	Neoadjuvant chemotherapy given No. (%)	NA	NA	NA
	Antiplatelet/anticoagulant use No. (%)	NA	NA	NA
	TM No. (%)	0 (0%)	0 (0%)	NA
	TM + SLNB No. (%)	0 (0%)	0 (0%)	NA
	MRM No. (%)	3 (100%)	0 (0%)	NA
	MRM + LVA No. (%)	0 (0%)	0 (0%)	NA
Re-operative hematoma within 30 d				
	Age (mean)	67	72.9	.457
	BMI (mean)	27.8	32.1	.375
	Albumin level (mean)	3.9	4.1	NA
	Neoadjuvant chemotherapy given No. (%)	1 (100%)	0 (0%)	1.000
	Antiplatelet/anticoagulant use No. (%)	2 (40%)	3 (60%)	1.000
	TM No. (%)	0 (0%)	0 (0%)	NA
	TM + SLNB No. (%)	2 (40%)	3 (60%)	1.000
	MRM No. (%)	1 (100%)	0 (0%)	1.000
	MRM + LVA No. (%)	0 (0%)	0 (0%)	NA
Seroma drainage within 30 d				
	Age (mean)	78.3	57	**.003**
	BMI (mean)	28.4	26.6	.735
	Albumin level (mean)	NA	4.3	NA
	Neoadjuvant chemotherapy given No. (%)	0 (0%)	6 (100%)	**.002**
	Antiplatelet/anticoagulant use No. (%)	3 (100%)	0 (0%)	.061
	TM No. (%)	0 (0%)	0 (0%)	NA
	TM + SLNB No. (%)	4 (100%)	0 (0%)	**.015**
	MRM No. (%)	1 (50%)	1 (50%)	1.000
	MRM + LVA No. (%)	0 (0%)	5 (100%)	**.015**
Wound dehiscence within 30 d				
	Age (mean)	69.4	77.6	NA
	BMI (mean)	69.4	77.6	NA
	Albumin level (mean)	4	4.5	NA
	Neoadjuvant chemotherapy given No. (%)	2 (100%)	0 (0%)	.333
	Antiplatelet/anticoagulant use No. (%)	1 (50%)	1 (50%)	1.000
	TM No. (%)	0 (0%)	0 (0%)	NA
	TM + SLNB No. (%)	0 (0%)	0 (0%)	NA
	MRM No. (%)	2 (66.7%)	1 (33.3%)	NA
	MRM + LVA No. (%)	0 (0%)	0 (0%)	NA

Abbreviations: BMI = body mass index; LVA = lymphovenous anastomosis; MRM = modified radical mastectomy; NA = not available; SLNB = axillary sentinel lymph node biopsy; TM = total mastectomy.
Values with p-value <0.05 were bolded.

fields were contiguous between the breast and axillary cavities, it is impossible to know if seromas originated from the chest wall or the axilla. Additionally, drain placement and removal practices were not standardized. One surgeon frequently utilizes 2 drains rather than one within the mastectomy bed; there was not a difference in this surgeon's primary endpoint results when compared to other surgeons that used a single drain. Two surgeons had a higher rate of seroma drainage than others that was found to be significant ($P = .041$); however, given that this was performed at the discretion of the surgeon, it is unclear whether there were additional factors contributing to this difference.

Additional studies at multiple institutions could further address whether this data is applicable to other practice settings and surgeons. This could also further evaluate any delays related to complications and whether MPP affects adjuvant care. A larger sample size would also potentially better identify differences between the groups with and without MPP, given the low occurrence rate of complications. A cost analysis could also be performed to further evaluate the use of this agent and complications; at our institution, a 3-g unit of MPP costs $166.00 and 1-g unit costs $93.00. Our study provides additional data to evaluate the outcomes of mastectomy patients treated with this hemostatic agent.

Conclusion

The use of MPP was not associated with a significant difference in antibiotic prescription, infection drainage, hematoma, readmission, dehiscence, or time to drain removal.

Subset analysis suggests that MPP use may have a role in patients undergoing axillary surgery, specifically LVA.

Clinical Practice Points

- MPP are used for surgical hemostasis. Our original study aims to promote high-quality care to breast surgical oncology patients through additional safety evaluation of this product. Existing data regarding this hemostatic agent is inconclusive to its benefit; a prior randomized control trial for this product in breast surgery patients required early closure related to funding. MPP remains a well-utilized hemostatic agent at our medical center, although its effects have not been evaluated retrospectively for our patient population. Given these considerations, we aimed to evaluate outcomes for mastectomy patients without reconstruction treated with and without MPP. We did not note a difference between the treatment groups, in terms of hematoma, infection, or time to drain removal. Our findings suggest that MPP can be considered in patients undergoing axillary surgery, such as lymphovenous anastomosis, to potentially reduce the risk of seroma.

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Disclosure

None.

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