

Original Research Article

Impact of microporous polysaccharide haemostatic agent on patients undergoing mastectomy or axillary dissection on seroma formation and timing of drain removal

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ABSTRACT

Background: Seroma formation is a known complication following mastectomy and axillary lymph node dissection (ALND) leading to morbidity and financial implications for patients. ARISTA™ AH has been designed to prevent postoperative seromas formation *in vitro*.

Methods: We performed a single institution, single surgeon retrospective study from January 2017 to December 2022 in patients undergoing mastectomy/axillary dissection to evaluate seroma formation rates and timing of drain removal.

Results: A total of 72 cases were included in our retrospective review of electronic medical records. Of these, 40 patients underwent ipsilateral mastectomies with sentinel node biopsies, 8 patients underwent bilateral mastectomies, and 18 patients underwent axillary dissections without concurrent mastectomy. Our analysis showed a non-significant decrease in seroma formation when ARISTA™ AH was used intra-operatively (10%) compared to standard care (24%), ($p=0.14$). The ARISTA™ AH group had a statistically significantly longer mean drain removal time than the standard care group (12.9 vs 7.6 days, $p=0.002$).

Conclusions: There was a trend towards lower seroma formation and a significantly longer requirement for drain placement after mastectomy in ARISTA™ AH group. Further research including randomised controlled multi-centre study evaluating the benefit of topical haemostatic agents in reducing seroma formation in breast surgery is warranted.

Keywords: Breast seroma, Mastectomy, ARISTA, ALND

INTRODUCTION

Breast cancer has become the most diagnosed cancer and the fifth leading cause of cancer-related death worldwide and contributes significantly to cancer surgical caseload.¹ In most cases with locoregional spread from breast cancer, patients requiring axillary lymphadenectomy undergo clearance of level 1 (lateral to pectoralis minor) and level 2 (behind pectoralis minor) lymph nodes. Level 3 (medial to pectoralis minor) lymph node dissection is

reserved for patients with clinically or radiologically involved nodes. A seroma is defined as a serous fluid collection which develops underneath the skin flaps following mastectomy or in the axillary dead space following axillary lymphadenectomy. Seroma formation is the most common complication following mastectomy with or without ALND (incidence 15-85%), followed by wound infection and haematoma formation, 2.9% and 4%, respectively.² These complications can delay adjuvant treatment such as chemotherapy/radiotherapy while complication is treated.

Seroma formation is hypothesized to result from an acute inflammatory reaction after surgical trauma to increase serous fluid in response to increased fibrinolytic activity in serum and lymph.³ Various patient related risk factors that contribute to increased risk of seroma formation post operatively following surgical management of breast cancer include increasing age, high BMI, breast volume, locoregional spread to axillary lymph nodes, previous ipsilateral wide local excision for breast cancer, poor surgical technique including tissue handling, use of heparin and/or tamoxifen treatment. Surgical management for breast cancer has undergone a paradigm shift from Halstead's radical mastectomy to breast conserving procedures like wide local excision. Similarly, sentinel lymph node biopsy has minimised the need for ALND. These changes have been accepted and adapted globally leading to a revolution in breast cancer management with consequently decreased seroma formation rates.³ Surgical techniques have also evolved to minimise the risk of seroma formation including skin flap suturing to minimise anatomical dead space, ligating lymphatics, better haemostasis with energy devices, using fibrin glue, and sealants. One of the most common practices worldwide to obliterate surgical dead space is the placement of suction drains, which assist in wound healing, reduce risk of infection, wound necrosis, and dehiscence.³ However, these drains can be left in place for days to months until the drainage volume subsides prior to consideration of drain removal to reduce risk of seroma formation contributing to overall disease burden and anxiety for patients.

Microporous polysaccharide haemostatic agent based on plant starch (ARISTA) has been proposed to reduce seroma formation, haematoma, and infection in surgical wounds.⁴ It has been in use in the United States of America since 2006, but remains a relatively new product in Australia, with approval for use by therapeutic goods administration being granted in 2016. ARISTA is an absorbable haemostatic agent derived from purified plant-based starch. Intra-operative use of ARISTA induces rapid coagulation, reduces blood loss, and is completely degraded in 24-48 hours *in vivo*.⁴ *In vitro* studies demonstrate that ARISTA promoted less of a pro-inflammatory response and was mostly degraded after 12 hours and completely after 3 days compared to other plant starch haemostatic agents such as STARSIL, thereby reducing the risk of foreign body reaction as well.^{4,5} Despite this, there has been little investigation into the use of ARISTA in breast cancer surgery and seroma formation.

Our hypothesis is that use of microporous polysaccharide particle haemostatic agent (ARISTATM) will reduce seroma formation after breast cancer surgery and facilitate early removal of drains. Reducing seroma formation has the potential to reduce complicated wound healing and surgical site infections rates, drain infection rates, delay to commencement of adjuvant treatment, poor mental health days, financial cost for the patient and

healthcare system. Since seromas are thought to be due to the inflammatory reaction following surgical trauma, we hypothesize that ARISTA use will counteract this effect and decrease the volume of fluid that settles in the dead space. Whilst use of ARISTA is well described in cardiothoracic and gynaecology surgery, especially in the USA, equivalent studies demonstrating use and efficacy in Australia is lacking. There is very little research published on the use of ARISTA in breast cancer surgery and on its efficacy in preventing seroma formation and influencing drain removal timing. This study will provide new information regarding the potential role of ARISTA in breast cancer surgery to reduce risk of seroma formation and facilitate early drain removal.

METHODS

Continuous sampling was conducted of patient records at Bankstown-Lidcombe hospital who underwent mastectomy (simple, modified radical or partial) with or without ALND for breast cancer from January 2017 to December 2022 performed by a single surgeon. These records were divided into two cohorts of patients who underwent mastectomy or isolated axillary dissection either with or without use of ARISTA. We compared a cohort of patients from 2017-2018 who underwent surgery without ARISTA to a cohort of patients from 2019-2022 who underwent surgery where ARISTA was used routinely intraoperatively. All patients had Blake drains placed intraoperatively to encompass the breast and axillary surgical space. None of the patients included in the analysis had neoadjuvant radiotherapy and/or chemotherapy.

Any patients undergoing either partial mastectomy (i.e., lumpectomy) with/without sentinel node biopsy, having immediate autologous reconstruction, and patients having simultaneous insertion of tissue expanders following mastectomy were excluded from analysis. Patient records with missing data proposed to have impact on seroma formation such as BMI, preoperative breast volume and ethnicity were excluded to avoid potential bias.

Surgical drains in the community were managed and removed by the community nurses in liaison with the surgical team. A drain output of less than 30 ml per day for two consecutive days was used as a criterion for removal. The drains were removed using aseptic technique by the nurses and promptly recorded in the patient's electronic medical record.

The primary outcome was incidence of post-operative seroma formation. The secondary outcome was average timing of drain removal post operatively. Other outcomes of interest were surgical site infection, haematoma, and wound dehiscence rates.

Statistical analysis was performed using unpaired t-test. The level of statistical significance was set at 0.05. The power prior to analysis was calculated to be 90% for a

cohort of 70 patients when considering a probable seroma incidence of 30% given the wide discrepancy in reported rates of seroma formation after breast cancer surgery.

RESULTS

A total of 72 cases were included in our retrospective review. Of these, 8 patients underwent bilateral mastectomies, and 18 patients underwent axillary dissections without concurrent mastectomy. Standard care and the ARISTA™ group had 41 and 30 patients respectively with case matched demographics. Mean age of the patients that did not have ARISTA was 58 (with a range of 36 to 86 years). The mean age of patients that had ARISTA intraoperatively was 63 (with a range of 36 to 92 years).

In the standard care group, 10 patients (24.39%) developed seromas. Of these patients, 5 required drainage (50%), which was performed via aspiration during their postoperative clinic visit. None of the patients in either cohort required readmission to the hospital for surgical site infection secondary to seroma. In patients undergoing surgery with routine use of ARISTA intraoperatively, 3 patients (10.34%) developed seromas with only one patient requiring drainage which was performed in the clinic during postoperative review (Table 1). We found that the incidence of seroma formation was not statistically significant (p=0.14).

We found that the average drain removal time was 12.9 days in the ARISTA treatment group and 7.6 days in the standard care group which was statistically significant (p=0.002), (Table 2).

Table 1: Timing of drain removal post operatively.

Variables	Standard care	ARISTA™ group	P value
Drain removal timing (days)	7.6	12.9	0.002
SD	5.04	8.56	

Average drain removal time was significantly longer in patients receiving ARISTA intra-operatively versus the control group, (12.9 vs 7.6 days; p=0.002).

Table 2: Incidence of post-operative seromas.

Variables	Standard care (%)	ARISTA™ group (%)	P value
Seroma formation (%)	24.39	10.34	0.14
SD	43.48	30.99	

Average incidence of seroma formation in ARISTA group was 10.34% versus 24.39% in the control group which was not statistically significant, (p=0.14).

In addition, patients undergoing breast surgery with or without ARISTA neither group developed surgical site infections, haematomas, or wound dehiscence during the study period (Table 3). As all the procedures were performed by the same surgeon, there were no technical differences in operative approach.

Table 3: Distribution of post-operative complications in patients undergoing breast cancer surgery.

Variables	Standard care	Patients treated with ARISTA™
Age (mean±SD) (in years)	58.3±15.6	63±16.8
Procedure		
Mastectomy and SLNB	22	18
Axillary clearance	11	7
Bilateral mastectomy	5	3
Seroma formation	10	3
Seroma requiring drainage	5	1
Surgical site infection	0	0
Haematoma formation	0	0
Wound dehiscence	0	0

DISCUSSION

There have been multiple studies regarding use of ARISTA as a haemostatic agent which demonstrate mixed results with some studies demonstrating good efficacy and others having equivocal results. The expansion of use of ARISTA to prevent seroma formation after breast cancer surgery remains new with little dedicated research into the topic. *In vivo* studies demonstrate ARISTA does not provoke a foreign body response and is mostly degraded by 12 hours, and completely degraded by 3 days.⁴ It is hypothesized that the immunostimulatory and haemostatic properties of ARISTA would aid in prevention of postoperative inflammatory exudate accumulation as well as capillary and lymphatic leakage, thereby reducing the risk of seroma formation.

Although our results showed a reduced incidence of seroma formation in patients who had ARISTA intraoperatively over those who did not, it was not statistically significant. Interestingly, the ARISTA treatment group had a statistically significantly longer drain placement time than the standard care group (p=0.002). There were no wound infections in this study. In comparison, post-op wound infection rates reported in literature tend to range from 0-16%. A future study would

require at least 224 patients enrolled to detect statistically significant difference in seroma formation with 80% statistical power.

Several studies have investigated the use of other topical agents in reducing seroma formation as well as certain systemic pharmaceutical therapies in breast cancer and other major surgeries. There have been multiple studies investigating the use of fibrin glues most of which demonstrate mixed results with some reporting no difference and others reporting a decrease in seroma formation.⁵ Studies investigating application of topical thrombin do not demonstrate a reduction seromas formation. Other studies have explored use of tetracycline, which is a sclerosing agent and demonstrate mixed results with respect to its efficacy in reducing seroma formation.⁶ Systemic pharmaceutical agents such as somatostatin analogues octreotide and lanreotide have also been explored as candidates to reduce secretions which promote seroma formation with mixed results.⁷ It is difficult to draw overall conclusion due to significant differences in methodology, sample size, clinical and surgical diversity in ways in which these agents have been explored for preventing seroma formations after major surgery. Despite these multitudes of agents that have been explored, no single agent has been identified thus far as optimal for preventing seroma formation.

Furthermore, several studies have evaluated the relationship between time of drain removal and risk of seroma formation, with early drain removal associated with higher rates. Studies with late drain removal cited lower seroma incidence rates ranging from 0-29%. In our study, the drains were generally pulled out when output was less than 30 ml over two consecutive days. This resulted in average drain removal occurring at 7.6 days for patients that did not have ARISTA during surgery, and around 12.9 days for patients that received ARISTA intraoperatively. This may have contributed to our overall low rates of seroma formation independent of the use of ARISTA as well. Drain placement was part of the inclusion criteria for this retrospective study, thus all patients had drains *in situ* and standardized drain management plans which was usually less than 30 CC over 2 consecutive days as a criterion for removal.

Seroma formation

Dead space after surgical resection is liable to being filled with plasma and lymphatic fluid. It occurs between 15-85% of breast cancer surgery patients.⁸ Pathophysiology is multifactorial and not completely understood.

Kuroi et al identified heavier body weight, extended radical mastectomy (compared to simple mastectomy), and higher drain outputs in the first three days as moderate risk factors for seroma development after breast cancer surgery.⁹ Factors that were not significant were: duration of drainage, hormone receptor status, shoulder immobilisation, negative suction pressure, lymph node

status, number of drains, number of removed lymph nodes, drain removal on the fifth day postoperatively as opposed to low output, tumour stage, drain suction versus free drainage, and fibrinolysis inhibitor use.⁹ Practice of sentinel lymph node biopsy reduced seroma formation compared to ALND.⁹ Other studies, have found age, breast size, tumour size, body mass index, axillary node status, surgical technique, surgical devices, mechanical or chemical obliteration of dead space, and active shoulder mobilisation as risk factors for seroma formation or prolonged drainage after mastectomy and ALND.¹⁰ Longer surgery and higher rates of intra-operative blood loss were both associated with increased early seroma formation risk.¹¹

Axillary clearance and seroma formation

Comparing patients undergoing mastectomy with SLNB against those undergoing mastectomy with ALND, the SLNB group had lower discharge volume (333 vs 1456 ml) and lower incidence of prolonged fluid drainage (12% vs 31%).¹⁰ Lymph leak may also be a factor in seroma formation however robust evidence is lacking.¹² ALND alone is associated with an incidence of seroma formation between 3-85%.¹³ Furthermore, lymph node dissection is associated with a higher rate of peri-prosthetic seroma formation.¹⁴

Impact of seroma formation

The morbidity for seroma formation includes: pain, anxiety, infection, wound dehiscence, prolonged hospitalisation, delayed adjuvant chemoradiotherapy, and reconstructive flap necrosis.⁸ Excess appointments for further assessment, investigation, and treatment of seromas compound the financial cost of breast cancer surgery. Further surgery may also be needed for abscess drainage and/or redo reconstruction.

Prevention of seroma formation

There are a variety of technical methods to reduce seroma formation aimed at decreasing dead space and shear forces. Achieving a negative surgical margin without radical or extended resections thereby reduces the amount of remaining dead space. Fibrin has been advocated as an adhesive to help obliterate dead space however success is variable.⁸ Similar controversy was seen with tetracycline sclerotherapy.⁸ Talc has also been utilised with variable success to eliminate dead space.¹⁵ Immobilisation has also been advocated to reduce shearing forces.¹⁵

Medications to reduce the lympho-vascular leak in resection has been investigated. Octreotide has a modest benefit in reducing seroma drainage volumes and is used in controlling lymph leak.⁸ Tranexamic acid has been shown to decreased haematoma development after breast cancer surgery but had no impact on seroma formation in one study and was associated with decreased risk of haematoma and seroma formation in another study.^{6,16}

In breast cancer surgery, radical and extended mastectomies are performed less because of earlier detection through screening and trials showing excellent oncological outcomes with breast conserving surgery. Smaller surgical resections will have less residual dead space. A quilting suture technique which involves skin flap fixation to pectoralis major muscle has been associated with a lower clinically significant seroma incidence compared to conventional closure in breast cancer surgery (12.9% vs 62.3%).¹⁷

Drain placement appears to reduce the number of aspirations but not incidence of seroma development.⁸ The optimal number of drains, suction versus free drainage, suction pressure, and their location is disputed.⁸ Obviating drain placement may facilitate early discharge but are associated with more frequent follow-up appointments for drainage.⁸ Shoulder immobilisation is likely confounded by various prescriptions of immobilization and timing of drain removal.⁸

Comparing energy devices, Thunderbeat had the lowest incidence of seroma formation (16%) compared to Ligasure (44%), scalpel (24%) and electrocautery (64%).¹³ Use of Harmonic reportedly decreased seroma formation compared to electrocautery (8.3% vs 33.3%, $p=0.003$).¹⁸ Only one patient required aspiration of a seroma in a series of 80 patients treated with argon beam coagulation.¹⁹

Topical haemostatic agents are also being explored such as microporous polysaccharide hemospheres. One such plant-based product (ARISTA AH Absorbable Haemostat) aims to dehydrate and gelatinise blood through osmosis to accelerate the clotting process. In a small placebo-controlled study, there was no difference in the quantity of serosanguinous drainage between groups after undergoing mastectomy for breast cancer.²⁰ ARISTA™ AH has been approved for use in Australia since 2016. In cardiothoracic surgery, it has been shown to decrease post-operative blood transfusion volumes.²¹

Treatment of seromas

Seromas can be observed, treated percutaneously or surgically excised and debrided. Interventions need to weigh infection risk against symptomatic, therapeutic, or cosmetic relief for patients. Seromas less than 70 ml in size of which the patient is asymptomatic can be observed.²² Equally, if previously drainage volumes were small (less than 70 ml) then the seroma should be observed.²² Skin tension secondary to underlying seroma would be an indication for drainage for patient comfort and to facilitate adequate wound healing.²² Pain or shoulder mobility restriction is another indication for drainage for comfort and functional recovery.²² Obvious signs of infection at surgical site warrant consideration of either drainage or surgical debridement in addition to antibiotic therapy. Drainage in setting of reconstruction

prosthesis should be considered cautiously due to added risk of implant loss due to infection from aspiration.²²

A non-resolving seroma should be addressed percutaneously with drainage and sclerotherapy.¹⁵ This carries its own set of risks: bleeding, neurovascular damage and associated chronic pain, infection correlates with the number of aspiration requests, reconstructive implant damage and consequent implant loss. Seromas from which more than 50ml is drained have an increased recurrence rate.¹⁵

Marangi et al described their surgical technique for managing chronic seromas with a vacuum assisted closure (VAC) therapy. The idea was to simultaneously stimulate granulation tissue growth and reduce dead space.¹⁵ Resection of the capsule, debridement to healthy tissue, normal saline irrigation, closed drain placement followed by VAC application are performed. Final closure with closed suction drain placement occurred once there was abundant healthy tissue.¹⁵ Finally, open debridement should be considered for recurrent seromas and those associated with infection or skin necrosis.¹⁵

Limitations

The limitations of our study include its retrospective design. The surgeon involved was not blinded to treatment with ARISTA and this may have introduced bias. There was only one main breast surgical oncologist involved which eliminates variations in practice with respect to decision to use ARISTA, threshold to drain seromas, and decisions regarding thresholds for drain removal. Though it was an electronic medical record analysis in our study, many of demographics pertaining to seroma formation specifically including ethnicity, BMI, and preoperative breast volume were not recorded. Furthermore, when comparing ARISTA to standard care, the total volume drained in each group was unavailable which should be examined in a prospective study.

CONCLUSION

Modern breast cancer surgery has been revolutionised by breast conserving surgery with proven effectiveness compared to radical mastectomy and ALND. Surgical morbidity has decreased however a multi-modal approach is needed to prevent seroma formation which remains highly prevalent. Small asymptomatic seromas may be observed however complicated or chronic seromas should be drained with a stepwise percutaneous then surgical approach. The financial impact and morbidity for patients with seromas following breast cancer surgery (mastectomies and axillary dissections) are well documented in literature. Novel agents like ARISTA which reduce seroma formation *in vitro* have been proposed. There was an increase in time to drain removal in patients receiving ARISTA compared to those who did not receive it. Future randomised control trials need to be designed to address whether ARISTA and other similar

haemostatic agents have a role to play in preventing seroma formation.

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