original contributions

Is There a Relationship Between Frequency of Port-Care Maintenance and Related Complications in Patients With Cancer?

Tali Lang, PhD¹; Sarah Jaboury, MD¹; Alexander West, MD¹; Jo O'Sullivan, BN²; Kirsten Seletto, GradDipCaN³; Lucy Wilson, MPharmPrac⁴; Elizabeth Gleisner, BN⁵; and Gary Richardson, MD^{1,6}

QUESTION ASKED: Does extending intervals between maintenance port flushes from monthly to every 12 weeks increase the incidence of port-related complications resulting in removal in cancer patients with implantable chest ports?

SUMMARY ANSWER: The findings from this study show that extending intervals between maintenance port flushes from monthly to every 12 weeks in patients with cancer who have completed therapy does not increase the number of port removals or port-associated complications.

WHAT WE DID: The onset of the COVID-19 pandemic in December 2019 prompted our health care center to examine current clinical practice in relation to maintenance port flush protocols. Current manufacturer guidelines recommend that implantable ports in patients with cancer not on active treatment complete monthly flushes to maintain patency of the port and minimize portrelated complications. To date, no prospective study has been conducted to evaluate the medical safety of extending flush intervals from monthly to every 12 weeks within a heterogeneous disease cohort. To reduce patient visits to hospital during the height of the COVID-19 pandemic, we extended intervals between maintenance port flushes to every 12 weeks in patients diagnosed with both solid tumor and hematologic malignancies who had retained their port following completion of therapy. Clinical data were extracted for 1,059 participants. The primary end points of this study were the overall number of ports removed and incidence of port-related complications reported between cohorts 1 and 2 (flushes every 4-8 weeks), and cohort 3 (flushes every 12 weeks). Participants were surveyed regarding preferences for maintenance port flushes.

WHAT WE FOUND: Across all three study cohorts no difference was observed in the overall percentage of ports removed because of physician-reported complications (25%-30%). In all groups, the percentage of port-associated complications including suspected infection and malfunction was low, with no significant difference between cohorts 1 and 2 (8%), or cohort 3 (5%). Moreover, 89% of participants preferred maintenance port flushes to occur every 12 weeks.

CONFOUNDING FACTORS AND DRAWBACKS: Use of deidentified data prevented us from conducting clinical follow-up and evaluating potential correlations between patient clinical outcomes, comorbidities, and port removals.

REAL LIFE IMPLICATIONS: In this study, we demonstrate that extended port flush protocols of up to 12 weeks appear safe and yield comparable clinical outcomes in terms of port-associated complications compared with more frequent port flush protocols. Importantly, patient feedback also supports a longer interval between port flushes as a component of patient-centered care for patients who are no longer on active treatment.

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PURPOSE Totally implantable ports require regular maintenance to prevent port-related complications. Manufacturers recommend monthly maintenance port flushes for patients for the life of the port. Previous studies show that extending intervals between maintenance port flushes up to 16 weeks does not increase incidence of port-related complications. To date, no prospective study has been conducted to evaluate the medical safety of extending flush intervals from monthly to every 12 weeks within a heterogeneous disease cohort. Research Question: Is it feasible and medically safe to extend intervals between maintenance port flushes to every 12 weeks in patients with cancer not on active treatment?

PATIENTS AND METHODS This study enrolled oncology and hematology patients who had retained their port following completion of anticancer treatment. Clinical data were extracted for 1,059 participants. The primary end points of this study were the overall number of ports removed and incidence of port-related complications reported between cohorts 1 and 2 (flushes every 4-8 weeks), and cohort 3 (flushes every 12 weeks).

RESULTS Data were allocated into three study cohorts on the basis of year and duration between port flushes. No difference was observed in the overall percentage of ports removed because of physician-reported complications across all cohorts (25%-30%). No change in the incidence of port-related complications including suspected infection and malfunction was observed between cohorts 1 and 2 (8%), or cohort 3 (5%).

CONCLUSION Our findings show that extending maintenance port flush intervals to 12 weeks does not increase the incidence of port-related adverse events and is medically safe.

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INTRODUCTION

Implanted ports are commonly used in the oncology setting as they provide long-term, easy central venous access for drug and treatment-related administrations.14 However, port usage may be associated with complications including infection, venous thrombosis, catheter occlusions, tip malposition, migration, and malfunction.⁵ To ensure patient safety and limit the number of possible port-related complications, manufacturer guidelines recommend that implantable ports at the completion of therapy should undergo monthly maintenance flushes.⁶⁻⁹ However, no evidence-based data exist to support this recommendation or best practice for port maintenance, which includes flushing intervals. The onset of the COVID-19 pandemic in December 2019 prompted health care provider Cabrini Health to examine current clinical practice in relation to maintenance port flush protocols.

As patients with cancer are at higher risk of infection, we wanted to reduce the frequency of hospital visits by extending intervals between maintenance port flushes while ensuring the medical safety of patients. Initially Cabrini extended port flush intervals in patients not on active treatment from every 4 weeks up to every 8 weeks. However, with daily COVID-19 infections increasing alongside associated deaths, in August 2020, Cabrini and other Melbourne metropolitan health providers further extended intervals between maintenance port flushes to every 12 weeks. This change was supported by previous studies that reported that the number of port-related complications including thrombosis and infection did not increase when maintenance port flush intervals were extended beyond 12 weeks in patients who had completed therapy.¹⁰⁻¹³ Moreover, it has been reported that more frequent port access is associated with an increased

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incidence of port-related infection.¹⁴ However, the findings from these observational-based studies require more comprehensive investigations because of retrospective reporting, cohort size, and nonheterogeneity of disease within the study population. Despite the limitations of these studies, the findings suggest that extending intervals between maintenance port flushes are not associated with increased risk of obstructive or infectious complications. Therefore, the aim of this study was to prospectively evaluate whether the incidence of port-related complications as evidenced by port removal changes between participants receiving maintenance port flushes every 4-8 weeks compared with every 12 weeks in a heterogeneous cohort of patients with cancer not on active treatment.

PATIENTS AND METHODS

Study Design

We designed a prospective, observational study to assess whether extending maintenance port flushing intervals from every 4 weeks to every 12 weeks in patients with cancer not on active treatment resulted in increased incidence of port-related complications requiring port removal. Port procedural records and alteplase administration data for all cohorts were provided as deidentified reports. Consent was not required to access deidentified patient information. Implied consent was obtained from participants in cohort 3 on the basis of the completion of port questionnaires by nurses at scheduled maintenance port flush appointments. Participants in cohort 3 could opt out from participation by not completing questionnaires at the time of their maintenance flush appointment or communicating they wished to continue port flushes at more frequent intervals. This study was approved by the Cabrini Heath Research Governance Office (approval # 05-17-08-20).

Study Cohort

The study cohort consisted of patients with hematologic and solid tumor malignancy who had PowerPort implantable, single chamber central venous catheters (Bard Access Systems Inc, Salt Lake City, Utah), who attended Cabrini Health between September 2018 and August 2021. English-speaking patients, age 18 years or older, who retained their implanted port following completion of treatment were eligible for enrollment in this study. Cohorts were defined by year of attendance. Participants in cohort 1 attended scheduled monthly port flush appointments between September 2018 and August 2019, cohort 2 attended port flush appointments between September 2019 and August 2020 every 4-8 weeks, and cohort 3 attended port flush appointments between September 2020 and August 2021 every 12 weeks. All patients with nononcology indications or implanted with other types of ports were excluded from this study.

Port-a-Cath Questionnaire

A total of 200 deidentified questionnaires were completed by nurses for cohort 3 participants only, who attended scheduled maintenance port flushes every 12 weeks at Cabrini Day Infusion Units between September 2020 and August 2021. Questionnaires were used to collect participant demographic and clinical data including age, sex, port location, time since port implantation, time since last port flush, cancer diagnosis, and disease stage. Prescription medications were categorized and those with < 5% of the total number of responses classified as other. As questionnaires were deidentified, the total number of participants was unable to be determined.

Port Procedural Records

The total number of port implantations, removals, and clinical data were extracted from the Cabrini Health Medical Imaging clinical system between September 2018 and August 2021. Port-related complications were documented in the Medical Imaging clinical system by the referring physician requesting the port removal. Port-related complications were classified into five categories, namely, suspected infection, malfunction, migration, pain, and other. Port removals because of unknown reasons were categorized as other. Pathology reports from port tip swab microbiological cultures following port removal for suspected infection were used to quantify the number of microbiologically confirmed or negative swabs. All pathology reports from port tip swabs were provided as deidentified records.

Suspected Port Blockages Requiring Alteplase Administration

Data were extracted from Cabrini Health clinical systems to determine the total number of scheduled port flush appointments for patients with solid tumor and hematologic malignancy between September 2018 and August 2021. Suspected port occlusions in this study were identified as the number of patients requiring alteplase administration. The total number of alteplase administration appointments was recorded for each cohort. Clinical data including treatment indication and administrative status of participants receiving alteplase were recorded. Follow-up of individual cases was not possible because of the study design using deidentified clinical data.

Study Intervention

Historical clinical data were collected for cohorts 1 and 2 who received maintenance port flushes every 4-8 weeks between September 2018 and July 2020. Data for cohort 3 were collected prospectively between September 2020 and August 2021. Participants in cohort 3 were not on active treatment and would not require access to their port for at least 12 weeks. All participants enrolled regardless of prior flush schedule were then scheduled for maintenance port flushes every 12 weeks. Each port flush was performed following standard sterile precautions withdrawing 5 mL of blood before flushing with 2 \times 10 mL of normal saline.

RESULTS

Participant Clinical and Demographic Data for Cohort 3

A total of 200 questionnaires were completed for patients with hematologic and solid tumor malignancy not on active treatment at scheduled maintenance port flush appointments between September 2020 and August 2021 (Table 1). The mean age of participants was 66 years, and the participants were predominantly female (86%). The majority of participants had their ports implanted over 12 months before enrollment in this study (n = 124; 67%). The most common malignancies were gynecologic cancer (45%), gastrointestinal cancer (34%), and breast cancer (17%). The port was most commonly implanted in the right chest (78%), followed by the left chest (14%), with a median (interquartile range) interval of 12 (8-13) weeks between flushes.

Port-Related Complications

To compare possible differences in the number of ports removed between 4-8 weeks and the 12-week port flush protocol, data were extracted for 1,059 participants between September 2018 and August 2021. The total number of ports removed across all cohorts over the study period was 286 (37%), from a total of 773 insertions. The percentage of ports removed between cohort 1 (25%), cohort 2 (30%), and cohort 3 (26%) was comparable (Appendix Table A1, online only). Treatment cessation (n = 226; 79%) was the most documented reason for port removal by physicians (data not shown). The remaining ports removed were classified into five categories of port-related complications, namely, suspected infection, malfunction, migration, pain, and other. The total number of ports removed as a result of complications between 2018 and 2021 was recorded for cohort 1 (n = 24; 8%), cohort 2 (n = 23; 8%), and cohort 3 (n = 13; 5%; Fig 1A). No difference was observed in the proportion of ports removed between cohorts. Data from all three cohorts combined showed suspected infection (n = 43; 15%) to be the most common port-related complication leading to removal, followed by malfunction (n = 8; 3%), other (n = 4; 1%), and migration (n = 3; 1%). The numbers of port removals because of suspected infection were comparable between cohort 1 (n = 14; 4.9%), cohort 2 (n = 18; 6.3%), and cohort 3 (n = 11; 3.8%; Fig 1A). Furthermore, from a combined total of 43 ports removed because of suspected infection, 34 (79%) were reported as negative for microbial infection from port tip swab culture pathology reports (Fig 1B).

Scheduled Maintenance and Alteplase Port Flushes

Between September 2018 and August 2021, the total number of completed port flush appointments was

calculated for cohort 1 (N = 711), cohort 2 (N = 645), and cohort 3 (N = 419). In total, 1775 port flush appointments were completed with 85 (5%) requiring alteplase administration (thrombolytic agent; Table 2). Alteplase appointments were primarily completed in the outpatient setting (96%-100%) at scheduled appointments such as port flushes, blood collection, and medical interventions including computed tomography scans. Participants with solid tumors more frequently required alteplase administration in cohort 1 (n = 24; 3%), and cohort 2 (n = 20; 3%), compared with hematologic malignancies (1%-2%). In cohort 3, the number of participants requiring alteplase flushes were similar for both solid tumors and hematologic malignancies (n = 14 and 19; 3%-5%, respectively). Overall, the proportion of alteplase administrations between cohorts 1 and 2 (4%), and cohort 3 (8%), was comparable.

DISCUSSION

Implantable ports are used for a variety of reasons in patients with cancer within the treatment setting. It is important they are maintained following completion of therapy to ensure patency and limit associated complications. To the best of our knowledge, this is the first study to prospectively compare the incidence of portrelated complications resulting in removal when maintenance flush protocols are extended from 4-8 weeks to 12 weeks in a heterogeneous cancer patient population. We show no difference across all study cohorts in the incidence of port-related adverse events or number of ports removed as a consequence of complications. Despite the higher number of females represented in this study, attributed to a number of oncologists at Cabrini Health being recognized within the state as experts in the field of breast and gynecologic malignancies, we do not believe this influenced overall outcomes presented in this study.

In this study, we reported on the incidence of five physiciandocumented complications including suspected infection, malfunction, migration, pain, and other. Infection, venous thrombosis, and catheter occlusions are the most commonly reported complications associated with port usage in patients with cancer.¹⁵ Previous retrospective studies in smaller, disease-specific cancer cohorts reported that extending intervals between maintenance port flushes was medically safe and does not increase the incidence of portrelated complications including infection, thrombosis, and occlussion.¹⁰⁻¹³ These observations were supported in a larger, observational, multicenter prospective study that showed no difference in rates of port-related complications in patients receiving extended flush intervals (\geq 60 days), when compared with patients receiving more frequent flushes.¹⁶

In our study, the incidence of suspected port occlusions in 4-8-week and 12-week groups ranged between 3%-8%. This is lower than previously reported in a smaller

TABLE 1. Cohort 3 Participant Characteristics

Demographics	No. (%)
Records	200 (100)
Age, years	
Mean	66
SD	12.38
18-30	1 (< 1)
31-60	52 (26)
> 60	147 (74)
Sex	
Male	29 (15)
Female	171 (86)
Location of port	
Right chest	155 (78)
Left chest	28 (14)
Right arm	1 (< 1)
Not recorded	16 (8)
Port insertion, months	
< 6	19 (10)
6-12	47 (24)
> 12	134 (67)
Interval since last flush, weeks	
Median	12.0
IQR	(8-13)
Cancer diagnosis ^a	
Breast	35 (18)
GI	68 (34)
Gynecologic	89 (45)
Hematologic	6 (3)
Urogenital	3 (2)
Disease stage	
1	14 (7)
II	31 (16)
III	57 (29)
IV	24 (12)
Not recorded	74 (37)
Comorbidities	
Arthritis	42 (21)
Diabetes	12 (6)
Heart disease	16 (8)
Hypertension	46 (23)
Hypercholesterolemia	40 (20)
Stroke	4 (2)
Thromboembolism	13 (7)
Prescription medications	
(continued in next column)	

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 TABLE 1. Cohort 3 Participant Characteristics (continued)

Demographics	No. (%)
Analgesia	25 (13)
Anticancer	39 (20)
Anticoagulation	24 (12)
Antireflux	49 (25)
Cardioprotective	74 (37)
Diabetic medication	13 (7)
Enzyme replacement	14 (7)
Psychotropic	41 (21)
Steroid	18 (9)
Thyroid	14 (7)
Other	34 (17)

Abbreviations: IQR, interquartile range; SD, standard deviation. ^aOne patient had a dual diagnosis of breast and gynecologic

cancers, and was counted in both sections.

prospective study of patients with solid or hematologic malignancies, showing port occlusions occurred in 11.5% of patients.¹¹ The difference observed may be attributed to our larger, heterogeneous disease cohort. However, a limitation of our study is that we could not follow-up participants because of the study design using deidentified data. In future studies, it would be important to document whether port access or patency was resolved with alteplase administration, the cause of port occlusions, such as malfunction or obstruction, and subsequent medical interventions including port removal.

Port-related infection and thrombosis in oncology patients are known to be relatively low, collectively occurring in 2%-5% of patients undergoing port flushes every 40-90 days.^{16,17} Suspected infection was the most reported complication resulting in port removal in our patient cohorts. Further investigation revealed that 79% of ports removed for suspected infections were negative for infection by microbiological culture of port tip swabs following removal. This is an important finding and suggests that a large proportion of patients underwent unnecessary surgical removal of their port. The number of confirmed infections (19%) in our study is much lower than the 45%-75% reported in previous studies.^{18,19} The difference may be attributed to procedural practice or patient demographics in individual studies. For example, in a study by Lecronier et al, participants requiring port removal were admitted to intensive care units for suspected bloodstream infection compared with our outpatient cohort.¹⁷ The discrepancy in numbers presented between studies when reporting suspected versus confirmed cases of infection highlights a gap in best clinical practices. As described by Lecronier and colleagues, to microbiologically confirm infection, samples should be collected from several sites including the port tip, blood through the port, as well as blood from a peripheral vein. This approach provides a more

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FIG 1. Physician-reported complications requiring port removal. (A) The total numbers of ports removed because of suspected infection, malfunction, migration, pain, and other. (B) Microbiologically confirmed port tip infections for cohort 1 (n = 1; < 1%), cohort 2 (n = 5; 2%), and cohort 3 (n = 3; 1%). NA, not available.

comprehensive overview when trying to identify potential infectious pathogens such as *Staphylococcus* and *Candida*, and localization of infection before surgical removal of the port.

Collectively, clinical outcomes reported in previously published studies corroborate the findings reported in our study that extending intervals between maintenance port flushes up to 84 days (12 weeks) from 4 weeks is medically safe, and does not increase the incidence of port-related adverse events. It should also be noted that the actual incidence of complications across all cohorts reported in the current study is possibly lower, given port procedural documentation did not include current treatment status of the participant, and therefore patients on active treatment would have been included in our reporting.

When striving to improve delivery of cancer care, medical safety of the patient is paramount; however, the patient's quality of life must also be considered. Therefore, as part of this study, we engaged patients from cohort 3 to provide feedback on their preference for time frames in attending

maintenance port flush appointments while not on treatment. Feedback was collected at the time of their scheduled port flush appointments (Appendix Table A2, online only). Overall, feedback from patients showed that the majority (89%) preferred a 12-week interval between port flush appointments compared with 4 weeks. Reasons stated for extending intervals were mainly because of convenience (46% and reduced hospital visits (16%). This suggests that the majority of patients do not feel that extending intervals between flushes will compromise their level of care or pose an increased medical risk. Increasing intervals between maintenance port flushes may also lead to additional benefits for health care providers. Extending the time frame between port flushes would be expected to be more cost effective by reducing staffing resources normally allocated to perform this procedure in the outpatient setting. In future studies, it would be important to undertake a cost benefit analysis of extending intervals. This is an important aspect from both a health care organization and patient perspective, as some institutions

TABLE 2. Suspected Fort Occusions Requiring Alteplase Authinistration					
Clinical Parameters	Cohort 1 N = 711	Cohort 2 N = 645	$\begin{array}{l} \text{Cohort 3} \\ \text{N} = 419 \end{array}$		
Treatment indication, No. (%)					
Solid tumor	24 (3)	20 (3)	14 (3)		
Hematologic malignancies	4 (< 1)	12 (2)	19 (5)		
Participant status, No. (%)					
Inpatient	1 (< 1)	0 (0)	1 (< 1)		
Outpatient	27 (4)	32 (5)	32 (8)		
Appointments, No. (%)					
Completed	25 (4)	28 (4)	32 (8)		
Cancelled	3 (< 1)	4 (< 1)	1 (< 1)		

TABLE 2. Suspected Port Occlusions Requiring Alteplase Administration

and insurance providers in Australia do not cover the cost of maintenance port flushes, and these costs may be passed onto the patient.

Although data from multiple studies have shown that extended intervals between flushes is medically safe and does not lead to increased port-related adverse events, clinical practices and manufacturer guidelines have remained unchanged. Expanding the current study to a prospective, randomized controlled trial in a heterogeneous disease cohort would provide robust data to promote change in clinical practice and improve the quality of care to patients with cancer.

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Overall, our large, prospective, heterogeneous disease cohort study demonstrates that extended port flush protocols are noninferior to current monthly guidelines, consistent with previously published studies. Importantly, the consumer feedback presented in this study further advocates for a change in clinical practice to address the needs of patients and improve the quality of cancer care. Given the current situation with the COVID-19 pandemic and evidence-based data generated from this study, Cabrini Health continues to implement scheduled maintenance port flushes every 12 weeks for patients with cancer not on active treatment.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at DOI https://doi.org/10.1200/OP.22.00060.

AUTHOR CONTRIBUTIONS

Conception and design: Tali Lang, Kirsten Seletto, Gary Richardson Financial support: Tali Lang Collection and assembly of data: Sarah Jaboury, Alexander West, Jo O'Sullivan, Lucy Wilson, Elizabeth Gleisner, Gary Richardson Data analysis and interpretation: Tali Lang, Sarah Jaboury, Alexander West Manuscript writing: All authors Final approval of manuscript: All authors Accountable for all aspects of the work: All authors

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APPENDIX

	Total	Ports Inserted	Ports Removed
Participants	No. (%)	No. (%)	No. (%)
Cohort 1	405 (100)	303 (75)	102 (25)
Cohort 2	342 (100)	240 (70)	102 (30)
Cohort 3	312 (100)	230 (74)	82 (26)
Total	1,059 (100)	773 (100)	286 (100)

TABLE A1. Total Ports Inserted and Removed

TABLE A2. Participant Feedback

Question	Records (N = 200), No. (%)			
Participant preference (weeks between flushes)	4	12	Other	Not recorded
Responses	4 (2)	177 (89)	7 (3)	12 (6)
Reason				
Convenience	1 (25)	81 (46)	1 (14)	
Less hospital visits	0 (0)	28 (16)	0 (0)	
Risk reduction	3 (75)	0 (0)	4 (57)	
Other	0 (0)	3 (2)	0 (0)	
Not recorded	0 (0)	65 (37)	2 (29)	