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Original research

ACUPRESSURE IN HOSPITALIZED PEDIATRIC ONCOLOGY PATIENTS WITH FEBRILE NEUTROPENIA - A PILOT STUDY

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Abstract: Background/Objectives: Chemotherapy-induced neutropenia during cancer therapy may lead to treatment delays, chemotherapy dose reduction, and life-threatening infections. Acupuncture and related techniques have received increased interest in adult oncology, resulting in improved blood cell counts in several clinical trials.

Methods: This case disease-matched historical control pilot study sought to evaluate the effects of daily acupressure treatment on increasing the absolute neutrophil count of hospitalized pediatric oncology patients with febrile neutropenia. Twelve patients were enrolled with a median age of 15.8 years.

Results: All enrolled patients received daily acupressure treatments, and nonexperiences treatment-related adverse events. There was no trend towards decreased days to blood cell count recovery (p=0.352) and length of stay (p=0.431) in cases as compared to controls. This pilot study, comparing cases and matched historical controls, supports the feasibility of acupressure as a safe and accessible method of supportive care for pediatric oncology patients**.**

Conclusions: Further studies are needed to explore the role of and efficacy of acupressure to support blood cell count recovery in pediatric oncology.

Keywords: pediatrics, oncology, febrile neutropenia, acupressure, integrative medicine, complementary treatments.

INTRODUCTION Chemotherapy-induced neutropenia (CIN) is a common and expected side effect for patients undergoing cancer treatments [1]. Chemotherapy is directly cytotoxic and causes neutropenia by destroying rapidly dividing early precursor cells in the bone marrow that would otherwise eventually mature to form neutrophils [1]. Duration and severity of neutropenia are related to the intensity of the chemotherapy regimen, including dose and schedule of administration [1].

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Prolonged neutropenia can lead to treatment delays, reduction in chemotherapy doses, extended antibiotic use, and increased risk for potentially lethal infections [2]. Furthermore, CIN may lead to lengthy hospitalizations, which can affect patient quality of life and increase healthcare costs [3].

The occurrence of febrile neutropenia (FN) in pediatrics is estimated at 0.76 episodes per 30 days of neutropenia [1]. There are many possible causes for FN, including bacterial or viral infection, blood product transfusion, malignancy, and certain chemotherapy agents [4]. If patients with severe neutropenia, i.e., absolute neutrophil count (ANC) < 500/uL, become febrile, the standard of care is

hospitalization and administration of broad-spectrum intravenous antibiotics while monitoring blood cultures [5]. Criteria for discharge in hospitalized patients with FN include stability of clinic status and improvement of complete blood cell counts [6]. Medications, such as granulocyte colony-stimulating factor (G-CSF), stimulate the bone marrow to produce more neutrophils do exist but may not be appropriate for certain diagnoses. Furthermore, G-CSF is not without toxicities - including bony pain, nausea, fever, and anaphylaxis [7]. Additionally, patients may be neutropenic despite the use of these stimulatory agents. Therefore, there is a need for further investigation into all agents that may raise the ANC.

Complementary medicine may serve as a high-reward intervention with a low adverse event profile and is among one of the top naturopathic physical modality interventions [8]. Acupuncture has received increased interest in the Western world due to ease of use, safety, and accessibility, and is the most studied intervention in patients with cancer undergoing chemotherapy treatment [9]. Derived from ancient Chinese practices dating back more than 3000 years, acupuncture is known to have clinical evidence in chronic pain, sepsis, and inflammatory bowel disease [10]. Focusing on the concept of Qi or vital energy, applying pressure to specific acupoints works to redirect or unblock the flow of Qi to lead to a rebalance of the Yin/Yang dichotomy [11]. Optimum health exists when all components of vital energy (wood, water, fire, earth, and metal) are able to easily travel through the channels in bodies known as meridians [11].

Several clinical trials in adult oncology have been performed to study the effect of acupuncture and acupressure in improving chemotherapy-induced leukopenia (CIL). Chen et al in their systematic meta-analysis (n=31) demonstrated the positive immunomodulatory effects of acupoint stimulation on bone marrow suppressed by lung cancer therapy [7]. A similar systematic review of patients with breast cancer also supported the use of acupuncture to relieve CIL [12]. A sham-controlled clinical trial of acupuncture for CIN was conducted on 21 adults with ovarian cancer. A positive trend in white blood cell (WBC) count was noted in patients receiving 30-minute acupuncture sessions (2-3 times weekly, 10 total) as compared to the sham group [13]. In a randomized control trial (RCT) of 18 patients with colorectal cancer, those receiving 45-minute acupuncture (twice-weekly, 6 total) showed a consistent positive trend in WBC count and ANC [14].

Though intriguing, the exact mechanism for improving CIL, is yet not completely known. In China, where acupressure and acupuncture are widely used as adjuncts to chemotherapy, it is understood that acupuncture may promote the maturation of granulocytes [9]. Chao et al. reports that acupoint pressure may enhance immunity, relieve bone marrow suppression, and produce an antioxidant effect [15]. Their comprehensive systematic review confirmed that any type of acupoint stimulation was associated with improved CIL. In a placebo-controlled single-blind study, Karst et al. demonstrated a significant increase in the respiratory burst of neutrophils in patients receiving acupressure at the LI-11 acupoint, indicating that acupressure not only increases the number of neutrophils but may also increase functionality [16].

Acupressure is a needleless integrative medicine (IM) therapeutic modality. It is similar to acupuncture and stimulates similar specific acupoints by physical pressure. Acupressure has been used in pediatric oncology patients for other indications. For example, a recent trial demonstrated the ability of acupressure to aid in preventing nausea and vomiting from chemotherapy [17]. To the best of our knowledge and based on the literature review, we did not identify randomized controlled trials in pediatric oncology patients experiencing febrile neutropenia. We performed this pilot study to determine the feasibility, safety, and efficacy of utilizing daily acupressure in pediatric oncology patients admitted to the hospital for febrile neutropenia.

METHODS

Objective and Trial Design

The purpose of this non-randomized historical-control pilot study was to evaluate the effects of daily acupressure treatment using predetermined acupressure points on hospitalized pediatric oncology patients with FN. Our primary objective was to determine if this protocol decreased the time to blood cell count recovery, a requirement for hospital discharge. The metric used for count recovery was absolute phagocyte count (APC), which is absolute neutrophil count (ANC) plus absolute monocyte count (AMC). Cases were enrolled on a rolling

basis until the study period ended and followed prospectively. The control group consisted of historical pediatric oncology patients who did not receive acupressure. Cases were disease-matched to 2-3 controls by age, cancer diagnosis, and subsequent chemotherapy treatment protocol.

Recruitment and Study Setting

The providers that administered acupressure treatments included: 3 pediatric physicians (1 IM physician, 2 oncology fellows) and 1 pediatric IM nurse practitioner. All providers underwent acupressure training with the primary IM physician with ongoing oversight and direct supervision. Acupressure was performed manually by applying pressure to the acupoint for 60 seconds with the pads of the practitioner's fingers. Parental consent and patient assent were obtained for patients younger than age 18 prior to enrollment. Patient consent was obtained for patients older than 18 prior to enrollment. Participation was expressively voluntary, and all patients were able to withdraw from the study at any time, regardless of reason, expressed or otherwise.

Participants Eligibility Criteria

All pediatric oncology patients ≤ 25 years of age admitted to the University of Minnesota Masonic Children's Hospital with febrile neutropenia (ANC < 500/uL and temperature > 100.3F) actively receiving chemotherapy, regardless of cancer type, were offered enrollment. Enrollment occurred within 24 hours of hospital admission. The enrollment period was from October 2020 to September 2021. Patients were excluded from enrollment if they were post-stem cell transplant, enrolled in a phase 1 investigational study, and/or had received an investigational product within the past 30 days. Primary demographic information was collected, such as gender, race, ethnicity, and age (Figure 1).

Acupressure Technique

Enrolled subjects received daily acupressure treatments until APC recovery. The acupressure treatment occurred in the patient's hospital room. A short standardized protocol was developed under the guidance of an Integrative Medicine physician to target high yield acupressure points. The selected acupoints were treated

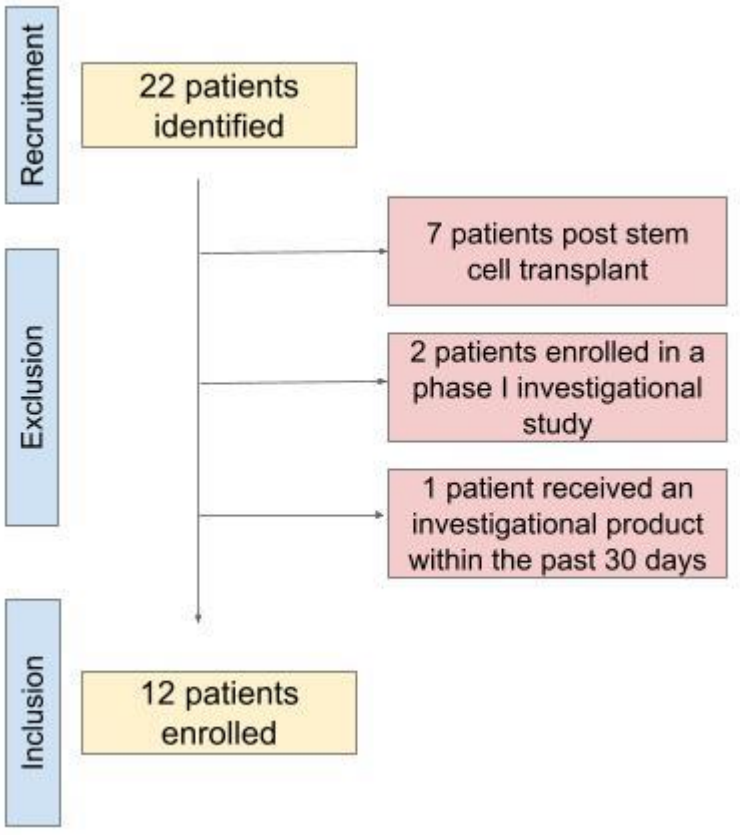

Figure 1. Inclusion and Exclusion Flow Chart.

for 60 seconds each. The acupoint regions included lower extremity (LR-3, SP-6, ST-36), hand (LI-4), upper extremity (LI-11), and torso (SP-21) (supplement 1). All patients received daily complete blood counts as per the hospital's febrile neutropenia protocol. Enrolled patients were monitored for adverse events using the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE).

Primary Outcome

The primary outcome was time to count recovery (APC ≥ 500/uL). APC was calculated by combining the absolute neutrophil count (ANC) and absolute monocyte count (AMC) from the daily complete blood cell count [18].

Secondary Outcome

Secondary endpoints included length of stay (LOS), platelet count recovery, and presence of bacterial isolate. The LOS was measured in days [19]. Platelet count recovery was defined as a platelet count of ≥ 20 x 10^9/L for at least two days without the need for platelet transfusion [20]. Presence of bacterial isolate was defined as the growth of a bacterium on culture medium within 48 hours of plating [21].

Ethical Considerations

Approval was received from the University of Minnesota Institutional Ethics Committee and Institutional Review Board in accordance with the Helsinki Declaration (September 6th, 2020, #103998).

Statistical Analysis

The initial power analysis identified an accrual goal of 35 patients. Descriptive statistics were utilized to analyze the collected data. Time variables, including time to APC recovery and LOS, were analyzed using the non-parametric Wilcoxon rank sum test. Tests were two-tailed, and a p-value of < 0.05 was considered statistically significant. Statistical analysis was performed using the statistical analysis system 9.4 (SAS Institute, Inc., Cary, NC).

RESULTS

Twelve patients were enrolled during October 2020 - September 2021. They were group-matched to thirty-four historical controls, which were pulled from the electronic medical record, admitted January 2015 - October 2019. One patient was removed from the study early due to contracting COVID-19 in an effort to conserve personal protective equipment (PPE) when the supply was limited. Among the cases, the majority of patients were female (75%, n=9) and White (91.7%, n=11). The distribution of gender and race was similar in the case group. Of the eligible patients approached for the study, only one elected not to enroll, and none electively stopped the intervention early. Baseline patient demographics are listed in Table 1.

	Cases (n=12)	**Controls (n=34)**
Female gender (n,%)	9 (75.0)	18 (52.9)
Race (n, %)		
White	11 (91.7)	30 (88.2)
Black	1 (8.3)	1 (2.9)
Asian	0	3 (8.8)
Hispanic (n,%)	0	2 (5.9)
Age at discharge, years (median, range)	15.8 [2.1/23.3]	12.2 [2.3/23.9]

Table 1. Patient Demographics.

There was no difference in platelet count recovery between the two groups. One of the 12 cases and 3 of the 34 controls had positive blood cultures. All enrolled patients were able to receive their daily treatments, and nonexperience treatment-related adverse events (Table 2). There was no trend towards decreased days to blood cell count recovery and length of stay in cases as compared to controls. In the acupressure cohort, patients with leukemia demonstrated a delay to blood cell count recovery with a longer length of hospitalization stay, as compared to the control group. Unfortunately, the pilot study did not enroll an adequate number of patients to reach sufficient statistical power.

DISCUSSION This study did not demonstrate a statistically significant impact of acupressure on APC recovery in this pediatric population despite a heterogeneous but limited sample size (n=12). This patient population was also very heterogeneous in terms of the underlying diagnosis, as patients with both leukemia and solid tumors were included. This is in contrast with most of the adult studies, which have been conducted within more discrete populations such as breast, gynecologic, or colorectal cancer [11-13]. There was no trend towards decreased LOS in cases as compared to controls. There was no difference in platelet count recovery among groups. One enrolled patient (n=12) had evidence of a positive blood culture, and 3 patients (n=34) in the control group had a positive blood culture. Interestingly, patients with leukemia who received acupressure tended to demonstrate a delay in blood cell recovery with longer LOS than their disease-matched historical controls. This may be due to changing standards of care for chemotherapy in the rapidly advancing field of leukemia. Additionally, the immune response in patients with leukemia after chemotherapy is a complex and unique process. Ultimately, this pilot study did not deliver statistically significant findings due to low power. This was due, in part, to the impacts of the COVID-

Days to blood cell count recovery (APC ≥ 500/uL)					
	Cases		**Controls**		P-value[1]
Cancer Type	*Median [Range]*	N	*Median [Range]*	N	
Solid tumor	3.0 [1.0/6.0]	8	3.0 [1.0/10.0]	23	
Leukemia	12.0 [4.0/19.0]	4	5.0 [1.0/21.0]	11	
All cancer types	3.0 [1.0/19.0]	12	3.0 [1.0/21.0]	34	0.352
Length of hospital stay in days					
	Cases		**Controls**		P-value[1]
Cancer Type	*Median [Range]*	N	*Median [Range]*	N	
Solid tumor	3.09 [1.65/6.36]	8	2.81 [1.09/21.46]	23	
Leukemia	13.82 [4.48/18.96]	4	4.93 [1.78/17.62]	11	
All cancer types	4.94 [1.65/18.96]	12	3.43 [1.09/21.46]	34	0.431

Table 2. Blood Cell Count Recovery and Length of Stay in Cases vs Controls.

19 pandemic, including necessary restrictions on elective research protocols during the study period and the need to limit the excess use of PPE when possible. Each patient was only enrolled once during the study period, despite several having multiple hospital admissions for FN, and it may have been fruitful to re-enroll them for each FN admission.

There was also a lower number of FN admissions as a whole during the study period versus prior years. This may have been due to widespread preventative stay-at-home orders in the early days of the COVID-19 pandemic. Where patients previously freely attended social gatherings and returned to school, this was no longer an option, likely limiting the risk of infectious exposure and subsequent fever. Further, the strict enrollment period of the first 24 hours from admission reduced the total possible enrollment.

Acupuncture presents a unique, pediatric-friendly non-pharmacologic intervention to support count recovery in CIN. Acupressure is a non-invasive technique that stimulates specific acupoints and may be more acceptable to pediatric patients as it is needle-less. Application of acupressure may be performed by bedside nurses, caregivers, or even patients themselves. The effect of acupressure in cancer patients on count recovery has had limited investigation. In one RCT, 28 patients with gynecological cancer were taught how to self-stimulate selected acupoints (15 points, 5 minutes each, 3 times daily x 5 days). A significant increase in WBC count was not observed; a borderline increase ($p=0.051$) in the mean difference of stem cell factor (SCF) was noted in the acupressure group [1]. SCF is an endogenous mediating cytokine important for bone marrow cell proliferation and differentiation [22]. Another previous study demonstrated that acupuncture and acupressure both improved cancer-related fatigue; invasive acupuncture was more effective [23]. In future studies, consideration for a combination of acupuncture followed by acupressure for maintenance or a longer study period may result in the efficacy of acupressure treatments for count recovery.

Of particular importance, an acupuncturist is not required to administer the treatments. Rather, medical staff or specialty-trained health care providers can be trained by a provider experienced in acupressure/acupuncture on a few targeted acupoints. This makes the intervention potentially more accessible and low-cost. As nurses represent the first line of patient assessment, future studies would likely enroll more patients by training bedside nurses to perform acupressure [24]. Additionally, with increased accessibility, acupressure sessions could be offered more consistently and more frequently. The bedside nurse would also obliviate the need for utilizing more PPE as they can group the acupressure sessions with their need to be bedside for other nursing duties. Additionally, there was interest from some families to receive training themselves to utilize the intervention as a potential ongoing non-clinician administered supportive care therapy.

Other limitations in this small pilot study include the possibility that noted trends were secondary to chance. Additionally, because this pilot study enrolled a broad diversity of cancer diagnoses, this may have skewed findings. The non-randomized, historical-control design of the study may have led to unintentional bias as cases were selected sequentially and respective controls were assigned after the fact. As this was a multi-investigator, non-blinded study, it is possible that there were unanticipated differences in technique that may have affected outcomes. Finally, enrollment was most certainly curtailed by the onset of the novel COVID-19 pandemic which affected the ability to offer expanded enrollment. This pilot acupressure study did not include auricular acupressure, which may be an important future direction to expanding enrollment.

CONCLUSION Our pilot study supports the feasibility of utilizing acupressure for hospitalized pediatric oncology patients with FN based on assessments of safety, acceptability, and compliance. No enrolled patients experienced treatment-related adverse events supporting the safety of the intervention. Further studies are needed to explore the role of acupressure in improving neutropenia in pediatric oncology patients undergoing active chemotherapy and how this practice can be successfully implemented in daily inpatient hospitalization care.

Conflicts of interest: The authors declare no conflicts of interest.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study is available on request from the corresponding author.

Abbreviations: the following abbreviations are used in this manuscript:

ANC	Absolute neutrophil count
APC	Absolute phagocyte count
CIL	Chemotherapy induced leukopenia
CIN	Chemotherapy induced neutropenia
FN	Febrile neutropenia
IM	Integrative medicine
LOS	Length of stay
RCT	Randomized control trial
SCF	Stem cell factor
WBC	White blood cell

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