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Home Point of Care INR Testing in Left Ventricular Assist Device Patients: A Clinical Evaluation

Emily Corsentino
University of Kentucky, emily.kiesler@gmail.com

Home Point of Care INR Testing in Left Ventricular Assist Device Patients: A Clinical Evaluation

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Emily Corsentino, BSN, RN, CCRN

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Abstract

Purpose: The purpose of this project was to evaluate the complications and adverse events in LVAD patients when comparing those using home point of care (POCT) international normalized ratio (INR) testing versus lab testing. Additionally, the time in therapeutic window for both these groups was studied. A cost benefit analysis was performed. All this data was compiled into a provider education evaluated by a pre and post-survey design.

Methods: The project is a single-center study that will occur at the University of Kentucky Chandler Medical Center. It is a cross-sectional, pre/post-test design. Data will be collected retrospectively starting January 2019, and prospectively for three months starting in October 2020. Complications and adverse events were collected through chart review. Time in therapeutic window (TTR) was calculated using the Rosendaal method. INR results were collected from the patient's medical record. A three question pre and post-test was used to evaluate provider understanding of the topic.

Results: 32 LVAD patients were evaluated for this study. Four providers completed the pre- and post-test with the educational video intervention. While there were more complications in the home point of care group, the results were not statistically significant (p=.15). Further evaluation of TTR yielded a higher TTR for the POCT group, however it was also not statistically significant (p=.17). There was also only a mild increase in provider understanding of the topic.

Conclusion: The findings from this study indicate that more research should be done on the topic. While there were more complications in the POCT group, they were not significant enough to warrant a move to utilizing all lab testing instead of POCT.

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Dedication

I would like to dedicate this project to my husband, my daughter, my family and friends. First, to my husband, thank you so much for support me through the years of schooling. I would not have made it to this point in my life without you. You were always there to push me through in the times that I wanted to give up. You are the reason that I am here, and I appreciate it more than you know. Second, to my daughter. I started this program for myself but I finished it for all of us. I want you to see that if you put your mind to it, you can complete anything. Finally, to my family and friends, thank you for listening to me stress about school these past years. Your constant words of encouragement helped me through.

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Background & Significance

Heart failure (HF) is a multifaceted disease process defined as "a structural or functional impairment of ventricular filling or ejection of blood" (Yancy et al., 2013, p. e246). From 2013-2016, HF affected roughly 6.2 million Americans, and it is projected to increase 46% by 2030. Symptoms include dyspnea, fluid retention, and pulmonary/peripheral congestion. The American College of Cardiology (ACC) and the American Heart Association (AHA) have categorized HF into four stages, from least to most severe. Stage A HF indicates no structural damage to the heart while Stage D HF is refractory to most treatments and requires interventions including pacemakers, left ventricular assist devices (LVADs), or heart transplants (Yancy et al., 2013). Unfortunately, there is no reverse staging. Once a person advances to a new stage of HF, despite treatment and improvement, they are unable to revert back to previous staging. There are many different guideline directed medical therapies (GDMTs) for the treatment of HF, and a large number of patients require these advanced interventions.

Although heart transplantation is considered the gold standard treatment for Stage D HF, the number of people requiring transplantation is on the rise, prolonging individuals' waitlist time. From 1987 to 2012, more than 40,000 people were waiting for heart transplants, while only 26,000 received a transplant (Yancy et al., 2013). With roughly 50% of those patients still waiting for an organ, the use of mechanical circulatory support (MCS) has been shown to be a viable option for these patients. LVADs are continuous flow devices implanted into the failing heart. They support the body by assisting the left ventricle in pumping blood through the circulatory system (Eisen, 2019). The 8th Annual INTERMACs report showed that between 2006 and 2016 there were 18,987 LVAD implants, with 26% of these listed for bridge to transplantation (BTT) and 50% listed as destination therapy (DT; Kirklin et al., 2017).

Decompensated HF is one of the leading causes of hospitalizations and readmissions in the United States (Yancy et al., 2013). LVADs have become the standard for decompensated HF as either BTT or DT. Adverse events, including thrombotic and bleeding events, cause severe complications for LVADs. Thrombotic events are defined as an ischemic stroke, transient ischemic attack and pump thrombus. Bleeding events are defined as gastrointestinal (GI) bleeding and hemorrhagic stroke (Nassif et al., 2016).

International normalized ratio (INR) is a blood draw lab test that examines clotting factors in the blood. The goal INR in LVAD patients is 2.0-3.0. According to Nassif et al. (2016), the ideal INR is 2.6. Patients have different INR goals based on previous complications such as previous bleeding or thrombus. Warfarin is a drug used to help maintain INR within these tight ranges (Schettle et al., 2018). Lab draws for INR must be drawn at certain intervals to ensure an optimal range for LVAD patients. Dionizovik-Dimanovski et al. (2015) point out that there must be a delicate balance of anticoagulation in these patients in order to avoid thrombotic and bleeding events. Home point of care testing (POCT) has been used in some patients to more closely monitor INR. Studies have shown that the percentage of time in the therapeutic window (TTR) is higher in those utilizing home POCT (Saleem et al., 2016; Dionizovik-Dimanovski et al., 2015; Schloglhofer et al., 2020; Bishop et al., 2014; Table 1). Home testing has become a more convenient way for providers and patients to control their INR.

Cost of testing a patient's INR is dependent on the method of testing they utilize. Furthermore, there are both direct and indirect costs the patient may incur. Direct costs include the actual testing supplies or charge to the patient. A study found that there was a $926 difference in cost over a 2 year span when looking at point of care testing versus lab testing (Phibbs et al., 2016). The authors of this study also looked at indirect costs to the patient such as

quality of life, time spent going to the clinic, and time taken out of work. It was concluded that those of use POCT had a higher quality of life score than those who went to the lab. Furthermore, they found that those who use home POCT had 21 fewer visits to the outpatient clinic, leading to less time taken off work, and a decreased cost to the patient.

Purpose

The purpose of this project was to evaluate complications in LVADs related to home POC INR results and clinical lab results. The specific aims were to:

1. Examine hemorrhagic and ischemic complications associated with home POC INR testing and clinical lab INR testing to evaluate a relationship between testing and complications.
2. Evaluate the percentage of time in therapeutic range TTR using the Rosendaal method in both patients using home POC INR testing and lab testing
3. Conduct a cost analysis to compare cost of home POC INR testing versus lab testing.

Theoretical Framework

The Common-Sense Model of Self-Regulation (CSM) was created by Howard Leventhal and is defined as "the processes by which patients become aware of a health-related threat, navigate effective responses to the treat, formulate perceptions of the threat and potential treatment actions, create action plans for addressing that threat, and integrate continuous feedback on action plan efficacy and threat progression" (Leventhal et al., 2016). This model looks at an individual's self-management of their health and the threats that accompany it. HF and LVAD patients must stay in-tune with their health and understand when there are threats, such as hemorrhagic and ischemic complications. The CSM provides a framework to evaluate an

individual's adherence to managing such threats (Leventhal et al., 2016). Each patient is responsible for their own health; however, practitioners must be available to help navigate the issues that accompany it.

The thought behind utilizing home POC INR testing is that participants will be able to immediately contact their provider with an abnormal result. Patients may be able to detect a complication before it becomes serious. This can also be considered recognizing a threat. If INR results are subtherapeutic or supratherapeutic, providers will be able to assess the situation and inform the patient of the best plan. In using home POC INR testing and not having to leave the house for weekly testing, patients feel in control of their health. This is the patient's action plan for preventing threat progression and managing possible threats to their health.

Review of Literature

A literature review was conducted in order to synthesis the evidence regarding home POC INR testing and outcomes in LVAD patients. This review included multiple databases from the University of Kentucky Medical Center Library including InfoKat Discover, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PubMed. Keywords for the search include, "left ventricular assist device," "LVAD," "heart failure," "home POC INR," "point of care INR," "mechanical circulatory support," "readmissions," "hospitalization," and "quality of life." Sixty-four articles were found using these keywords.

All articles used had to be written in English, involve humans 18 years of age and older, be published within the last 10 years, and be peer reviewed. Articles were excluded if they were full text, written before 2010, involved animals or children aged 0 years to 17 years, or were not written in English. After inclusion and exclusion criteria were applied, twenty articles remained, five of which pertained to this research (Table 1; Table 2).

Of the five articles that were reviewed, two showed a correlation between POCT and clinical venous lab testing (Dionizovik-Dimanovski et al., 2015; Schettle et al., 2018). Dionizovik-Dimanovski found that POCT can overestimate INR; however, the authors felt that the correlation between POCT and lab were still significant enough for utilization in LVAD patients. Alternatively, Schettle et al. (2018) performed a large multicenter study, in which they found that the correlation between POCT and lab testing showed no statistically significant overestimation in POCT.

Additionally, four studies showed that there was an increased percentage of time in the therapeutic range (TTR) for those utilizing home POCT (Saleem et al., 2016; Dionizovik-Dimanovski et al., 2015; Schloglhofer et al., 2020; Bishop et al., 2014). Saleem at al. (2016) found that the TTR in participants using home POCT was 52% compared to lab testing, which was only 36%. Bishop et al. (2014) and Schettle et al. (2018) assert that POCT is a viable option for LVAD patients who may not have the means to get to the lab consistently for INR testing. Furthermore, Saleem et al. (2016) and Schloglhofer et al. (2020) each found a significant decrease in hemorrhagic and thrombotic complications in LVAD patients who utilized home POCT. It is important to note that Bishop et al. (2014) did not find any statistically significant difference in complications between home POCT and lab testing.

There are certain gaps in the literature. First, there are multiple POC machines that are used for INR monitoring . Of the research that reviewed the correlation between home POCT and lab testing, each used a different machine. For example, Dionizovik-Dimanovski et al. (2015) evaluated the Alere INR machine, while Schettle et al. (2018) evaluated either the Alere or the CoaguCheck INR machines. Furthermore, none of the articles discussed testing costs. Overall, there is very limited research regarding home POCT and lab testing, and the outcomes

associated with each. Of the studies reviewed, only one study was performed at multiple centers, and most had small sample sizes. However, there were still significant data showing the benefit of home POCT with regard to TTR and complications in the LVAD population.

Methods

Design

The aim of this study was to evaluate INR results in LVAD patients who use home POC testing versus clinical lab testing in order to assess complications, TTR, and cost. The project was a single-center study that occurred at the University of Kentucky Chandler Medical Center. It was a cross-sectional, pre/post-test design. Data was collected retrospectively starting January 2019, and prospectively for three months starting in October 2020. After data collection from LVAD patients, an educational presentation on the results was sent to HF providers, along with pre- and post-test surveys. Variables for this project included patient demographics, LVAD type, HF class, home or lab INR testing, TTR, readmission rates, thrombotic complications, hemorrhagic complications, cost, and provider education.

Setting

University of Kentucky (UK) is an academic medical center enterprise located in Lexington, Ky. It is the largest medical center in Lexington including both in-patient care as well as clinics. Albert B. Chandler hospital opened in 1962 as an extension of UK Hospital and houses 569 beds in the acute care setting as well as 100 intensive care unit (ICU) beds. Additionally, the Gill Heart and Vascular Institute (GHVI), a part of UK HealthCare, is a nationally recognized center for the treatment of heart disease and stroke and was recognized in 2019 as a High Performing Hospital in Heart Failure by *U.S. News and World Report*. The

Advanced Heart Failure and Transplantation program is housed within the Gill Heart and Vascular Institute and was the primary location for this study.

UK HealthCare is committed to the three pillars of academic healthcare including research, education, and clinical care. Their mission is to provide advanced patient care, strengthen local healthcare, and support research and educational needs from the university. The vision of UK HealthCare is to achieve national recognition as a Top 20 public academic health care center while developing medical therapies for Kentucky and surrounding areas (University of Kentucky, 2020). Finally, the university operates under five DIReCT values which include: diversity, innovation, respect, compassion, and teamwork. Each of these values are used to help guide decision making and behaviors as well as foster a work culture dedicated to patient-centered care. This DNP project encompassed the mission, vision, and strategic plan of UK HealthCare by ensuring patient safety and quality of care during the entire study. Each patient was treated with respect and compassion. Additionally, the project itself was an innovative experience that allowed the University of Kentucky to utilize resources already available to other academic medical centers treating patients with advanced HF.

Several key stakeholders contributed to the success of this project. The Advanced Heart Failure Team at UK HealthCare agreed to support this project in its entirety. They are committed to giving quality care to their patients, helping to support patients' quality of life, and decreasing hospitalizations that may occur related to complications from uncontrolled INR levels. The results of this project could affect participants' physical, mental, and financial well-being, therefore they are also stakeholders in this project. The DNP student represents the primary stakeholder, as she was the one responsible for data collection and evaluation. Finally, the

College of Nursing at the University of Kentucky was invested in the DNP student's success and completion of this project and will benefit from successful outcomes.

Sample

Patients who were included were those with a) end stage HF, b) implantation of an LVAD device including Heartware (HVAD), Heartmate II (HMII), and Heartmate III (HMIII), and c) the ability to speak and write in English. Those excluded from this study were those who were a) less than 18 years of age and b) not on systemic anticoagulation at the time of adverse event. The target population for this study included patients undergoing treatment for advanced HF within the Gill Heart & Vascular Institute clinics. This population will include HF patients both with and without mechanical circulatory support. MCS Coordinators identified those who are appropriate to participate in the study.

A total of 33 participants consented to this study. A retrospective chart review was performed form January 2019 to September 2020. Participants were then followed until February 2021 to evaluate INR results and complications. Of these 33 patients, one was excluded due to not being on any anticoagulation at the time of their complication. Therefore, the final number included in the study was 32 patients. Furthermore, the provider education survey was sent to 53 participants. Of these, 11 surveys were started but only four were filled out completely.

Data Collection

Approval for this project was obtainted from the Institutional Review Board (IRB) at the University of Kentucky where the project was performed. After approval, MCS coordinators contacted potential participants regarding their willingness to be involved in the study. If willing, MCS coordinators went through informed consent and HIPAA documentation at the patient's next clinic appointment. During this time, participants also filled out a demographic survey

(Appendix A). After informed consent and HIPAA were obtained, the primary investigator (PI) began the study. Due to the COVID-19 pandemic, fewer potential participants were having in-person clinic appointments and opting for telehealth. Therefore, an IRB amendment was submitted for a "Waiver of Documentation of Informed Consent" and Form K "Waiver of HIPAA Documentation". Both documents were approved by the University of Kentucky IRB and Office of Research Integrity (ORI). These waivers also applied to providers who would receive the educational materials created.

Each participant was given a unique identification number known only to the PI. This was done in order to protect the participant's identity and create anonymous data. The crosswalk table to decode this identification number was kept on a separate spreadsheet. All information was kept on the University of Kentucky OneDrive behind an encrypted, password protected firewall. The educational video and pre/post-test surveys (Appendix B) were created in a streamline format through UK REDcap system. A link was created and sent to the LVAD Clinic List Serv that included physicians, advanced practice providers, pharmacists, and MCS Coordinators. Demographic data included age, gender, ethnicity, NYHA Class, and MCS device. Outcome variables included: patient demographics, LVAD type, HF class, home or lab INR testing, TTR, readmission rates, thrombotic complications, hemorrhagic complications, cost, and provider education. INR results were collected for each patient for the year 2020 and use to calculate TTR for each patient.

Data Analysis

Descriptive statistics, including means, standard deviations, and frequency distributions, were used to summarize study variables. Time in therapeutic window was compared between POC meter testing and lab testing using the two sample t-test. Adverse event rates were

compared between groups using the chi-square test of association. Provider knowledge items were evaluated pre and post using the paired sample t-test. All data analysis was conducted using SPSS, version 25 with an alpha of .05.

Results

Sample Characteristics

A total of 32 patients were chosen for this study after removal of inappropriate candidates. The average age of these participants was 51.8 years (SD 14.1; Table 3). Participants were primarily male (75%) with the remainder being female (25%). Caucasians made up 78.1% of the participants, and 21.9% were African American. Three LVAD types were studied, including; Heartmate 2 (25%), Heartmate 3 (34.4%), and Heartware (40.6%). The primary New York Heart Association (NYHA) HF class for participants was class II (46.9%), with the remainder as follows: class I (3.1%), class III (34.4%), and class IV (15.6%). Seventeen of the participants utilized home POCT (53.1%) with the remaining 15 (46.9%) participants using the lab to test their INR. Participants suffered from the following comorbidities: NICM (53.1%), ICM (34.4%), HFrEF (100%), pulmonary HTN (3.1%), CKD (40.6%), COPD (21.9%), CVA (21.9%), CAD (37.5%), Diabetes (40.6%), Pulmonary Edema (3.1%), HTN (71.9%), hyperlipidemia (37.5%), cirrhosis (9.4%), alcohol abuse (6.3%), anxiety/depression (34.4%), and hypothyroidism (9.4%). Four providers completed the pre-survey, educational video, and post-survey. Their roles were attending physician (25%; Table 4), fellow physician (25%), and MCS coordinator (50%).

Complications

Upon completion of a thorough chart review of all participants, it was determined that there were eight complications related to POCT (47.1%) compared to three in the lab testing

group (20%) with a *p*-value of .15 (Table 5). Statistical evaluation of all adverse events was completed using the chi-square test of association. Complications were broken down even further by category (hemorrhagic or thrombotic). Events that are considered ischemic include transient ischemic attacks (TIA), ischemic stroke, and pump thrombus. Three TIAs occurred total, two in the POCT group (11.8%) and one in the lab testing group (6.6%), with p=1. Two ischemic strokes occurred in the POCT group (11.8%) due to subtherapeutic INR with no events in the lab testing group (p=.49). One participant in the POCT group experienced a pump thrombus (5.9%), with zero in the lab group (p=1).

The hemorrhagic adverse event category includes subarachnoid hemorrhages (SAH), gastrointestinal bleeds (GIB), and hemorrhagic strokes. Two participants experienced SAH in the lab testing group (13.3%) with none in the POCT group (p=.21). Two participants experienced GIB (11.8%, p=.49), and one participant experienced a hemorrhagic stroke (5.9%, p=1) in the POCT group. There were no other complications in the lab testing group.

Time in Therapeutic Window

Time in therapeutic window (TTR) was calculated using the Rosendaal method. This calculation evlauates the percentage of time that the patient is in their designated INR range based on total days and total tests. Statistical analysis was completed using the two-sample t-test. There were 17 participants who utilized home PCOT with 15 participants utilizing lab testing. The mean TTR for the POCT group was 58.3% (SD=15.6) while the mean TTR for the lab group was 50.3% (SD=16.6) with a p value of .17.

Cost Analysis

Information for cost analysis was gathered from the durable medical equipment (DME) specialist utilized by the MCS and lab departments at UK. They found that the average cost for

home POCT testing for patients who have both private insurance and Medicare is roughly $20/month or $240/year (Table 8). For lab testing, the average cost for private insurance is $6/test. Therefore, if a patient tests roughly 50 times a year, the average cost would be $300/year. Alternatively, medically necessary lab tests are covered at 100% through Medicare when ordered by a provider.

Provider Education

The link for the pre and post survey, as well as the educational video on complications, cost, and TTR for LVAD patients, was sent to the LVAD Clinic List Serv at the University of Kentucky. This included roughly 53 potential participants including attending physicians, fellow physicians, APPs, pharmacists, and MCS coordinators. Of the 53 potential participants, 11 surveys were initiated but only four were completed. Demographic information can be found above and in Table 4. Total pre and post test scores were statistically calculated using the paired sample t-test. The mean total score for the pre-test was 50% (SD=19.6) while the mean total score for the post test was 66.8% (SD=27.4) with a *p* value of .39 (Table 6).

These data were further broken down by each question (Appendix B). The questions were yes/no style. The first question evaluated complication rates in POCT and lab testing. The pre survey mean was 0 with the answer from all four participants stating "no" to whether POC testing has more complications than lab testing (Table 7). Post test scores had a mean correct answer of 50% with a *p* value of .18. The second question evaluated cost benefit. Due to 50% of participants answering the pre-survey questions correctly, and 50% of participants answering the post survey questions correctly, the *p* value is 1. Finally, for time in therapeutic window, 100% of participants answered both the pre and post survey questions correctly (p=1).

Discussion

Complications

The collected data showed more adverse events in those who used home POCT than those who use lab testing. However, the data did not reach statistical significance. There were eight participants with complications in the POCT group and three in the lab group. It is important to note that while these data may not yield statistically significant results, in part potentially due to small sample size, that there is still a higher number of participants who experienced adverse events in the POCT group. This is different than the original hypothesis for this study, which was that there would be fewer complications in the POC group than the lab group, based on the literature review.

Time in Therapeutic Window

The time in therapeutic window also did not show a statistically significant difference between home POCT and lab testing (p=.17). While this may not have a statistical significance, it still does correlate with the original hypothesis. Home POCT is more convenient and allows them to have more control over their care. However, as these patients do not have to present to a clinic to have their labs drawn, they may miss some tests. Further study could evaluate the total number of tests versus total tests in range. This would allow the investigator to evaluate compliance in relation to time in therapeutic window.

Cost Analysis

There is mixed information when looking at the cost analysis of POCT versus lab testing. The cost to the patient is dependent on which insurance provider the patient uses. For private insurance, it appears that home POCT is most cost beneficial to patients. This is because for one month's worth of testing, a POC meter costs $20/month. For lab testing, the cost is roughly

$6/test. Therefore, the monthly cost is dependent on how many times the participant tests. If the participant tests five times a month this could cost $30/month. Alternatively, if the patient has Medicare insurance, the cost of the POC meter is the same as with private insurance. However, lab testing is free. In the end when it comes to cost, the patient's comfort level, willingness to participate, and understanding of the machine should weigh heavily on which testing route is used.

Provider Education

All the data were compiled into a provider educational video. This video, along with the pre- and post-test, were entered into the University of Kentucky REDcap system where a streamline link was provided. When evaluating the four providers that completed the surveys, there was no statistical difference in their cumulative scores (p=.39). Furthermore, the data were broken down into the three questions asked on the pre and post-test. For complications, no provider answered the question correctly. However, 50% answered it correctly post intervention, yielding a p of .18. The remaining two questions yielded p values of 1. None of these data are statistically significant. The small sample size may have contributed to this. While this survey link was sent to 53 people, only four responded. Furthermore, the cohort that this was sent to deals only with LVAD patients. They are familiar with the patient population and may be more familiar with the potential outcomes of this study.

Limitations

There were several limitations identified during this study. The first is the small sample size. In the original IRB application, informed consent and HIPAA authorization would be gained in person during the participant's clinic appointment. However, due to the COVID-19 pandemic, potential participants were not keeping their in-person appointments, or they were

opting for telehealth visits. Due to this, an IRB addendum was submitted for waiver of documentation of informed consent and waiver of HIPAA authorization. This led to a small sample size for LVAD participants. Additionally, only four providers completed the provider education. This sample size was also small and may have skewed the final results. Furthermore, this project was conducted at a single center. Multi-center studies allow for a larger sample size. Next, the retrospective and prospective nature of this study, which included chart review, was a limitation. This study was designed primarily on events and results that were charted in the patient's electronic medical record. This relied on the documentation of providers as to whether adverse events and INR results were entered into the chart correctly. Finally, this study was not a randomized controlled trial. Randomized controlled trials are the gold standard in research, and therefore the absence of randomization will be considered a limitation in this study.

Recommendations for Future Research

This study brought up several questions that could be directed towards future research. First, as there were more complications with those using home POCT, it may be beneficial to study the time it takes those patients to receive their warfarin dose adjustment. Also, it would be beneficial to look at the long-term outcomes of those who experienced adverse events in each group. Furthermore, additional research is needed on the reliability of home POCT. While a majority of the studies that have been performed found that POCT accurately correlates with lab testing, only a mild to moderate correlation was found between the two when results were >4.5 (Wool, 2018). More research is needed on how comorbidities affect home POCT and lab testing. Participants with underlying diseases affecting their coagulation may also affect their POC INR results. Additionally, those diseases may also affect their adverse events and outcomes. Finally, a more in-depth study should be conducted regarding indirect costs to the patient. Indirect costs

include patient's quality of life, time off work, and caregiver's time. Considerations must be made for the patient. If the patient has to take time off work, this is time they are not getting paid for thus an additional cost they will incur. Additionally, it is important to look at a possibility of improved quality of life for those patients who use home testing equipment.

Conclusion

This study produced different outcomes than originally hypothesized. While none of the data were statistically significant, there were clinically significant findings. Despite having more control over their testing and having a higher percentage of time in their therapeutic window, participants who utilized home POCT experienced more adverse events than the lab testing group. Additionally, providers experienced an increase in knowledge when it came to their understanding of adverse events in the home POCT group. Furthermore, cost to the patient is highly dependent on the insurance they use, their understanding of the equipment, and their willingness. This should be considered when making a decision about testing. It is important to broaden this study to multiple centers in efforts to gather a larger sample population. Comorbidities should also be evaluated to understand their effect on certain outcomes as well as looking at the long term outcomes of those who do experience adverse events. Finally, further research is needed on the number of tests in range compared to the number of tests administered when examining TTR. This would provide a better picture of a patient's compliance with testing as well as their overall understanding of the importance of their INR.

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Table 1. Literature review

Author, Year	**Study Design** **Study Purpose**	**Sample Characteristic Setting**	**Main Findings**	**Level of Evidence**
Saleem et al. (2016)	Retrospective To evaluate complications in LVAD patients using home INR testing versus lab testing. Complications were defined and thrombotic or hemorrhagic events	42 patients (26 home testing, 16 lab testing) Single center study	Patients who use home testing, tested fewer times than patients who used the lab 52% of patients who used home testing were within range 36% of patients who used lab testing were within range Patients who used home testing had fewer hemorrhagic complications (15% vs 25%)	IIIb
Dionizovik-Dimanovski et al., (2015)	Prospective, correlation study To determine the reliability of the Alere point of care machine versus clinical lab testing in patients with CF-LVADs	50 patients with LVADs on stable warfarin therapy for at least 3 weeks Single center study	Alere device consistently overestimate INR Home INR testing is more convenient and improves the % of time within targeted INR range Moderate correlation between Alere and lab testing ($p<0.001$)	
Schloglhofer et al., (2020)	Retrospective Review To evaluate if frequency of point of care INR	48 LVAD patients who use point of care INR testing	The % of INR within range was higher in those who	

	testing effects the quality of anticoagulation therapy, adverse events, and outcomes	(36 tested weekly, 12 tested 3 times a week) Single center study	tested daily (p=0.006) Well controlled INR had lower thrombotic and hemorrhagic events	
Bishop et al., (2014)	Retrospective cohort study To evaluate effectiveness patient self INR testing versus lab testing in LVADs	55 LVAD patients (44 lab testing, 11 self testing) Single center study	% of time within targeted range was higher in the self test group (p=0.026) No difference in complications between the two groups	
Schettle et al., (2018)	Retrospective, nonrandomized control study To determine whether POC INR versus plasma INR INR values differ in the LVAD population	279 patients with LVADs 7 centers, internationally	No statistical difference between POC verses plasma INR testing (p=0.001) No statistical difference in patients with and without GI bleeds (p=0.22)	

Table 2. Synthesis table to summarize findings

Synthesis Table					
Variables of interest (outcomes)	Saleem et al., (2016)	Dionizovik-Dimanovski et al., (2015)	Schloglhofer et al., (2020)	**Bishop et al., (2014)**	**Schettle et al., (2018)**
Hemorrhagic complications (POCT vs lab)	↓c	NE	↓b	ND (b)	NE
Thrombotic complications (POCT vs lab)	↓c	NE	↓b	ND (b)	NE
TTR in POCT	↑c	↑c	↑b	↑b	NE
Correlation of POCT and lab	NE	↑b	NE	NE	↑b
LEGEND: ↑=INCREASED; ⁻=DECREASED; NE=not evaluated; ND=no difference; POCT=point of care testing; TTR=% time in therapeutic range; [a] higher level evidence; [b] statistically significant; [c] statistical significance not reported					

Table 3. Descriptive summary of patient demographic and clinical characteristics (*N* =32)

Characteristic	Mean (SD) n (%)
Age	51.8 (14.1)
Gender	
Male	24 (75%)
Female	8 (25%)
Race	
Caucasian	25 (78.1%)
African American	7 (21.9%)
Language	
English	32 (100%)
Device Type	
Heartmate 2	8 (25%)
Heartmate 3	11 (34.4%)
Heartware	13 (40.6%)
NYHA Status	
Class I	1 (3.1%)
Class II	15 (46.9%)
Class III	11 (34.4%)
Class IV	5 (15.6%)
INR Check	
POC Meter	17 (53.1%)
Lab	15 (46.9%)
Comorbidities	
NICM	17 (53.1%)
ICM	11 (34.4%)
HFrEF	32 (100%)
pHTN	1 (3.1%)
CKD	13 (40.6%)
COPD	7 (21.9%)
CVA	7 (21.9%)
CAD	12 (37.5%)
DM	13 (40.6%)
Pulmonary Edema	1 (3.1%)
HTN	23 (71.9%)
HLD	12 (37.5%)
Cirrhosis	3 (9.4%)
Alcohol Abuse	2 (6.3%)
Anxiety/Depression	11 (34.4%)
Hypothyroidism	3 (9.4%)

Table 4. Descriptive summary of provider characteristics (*N=4)*

Characteristic	Mean (SD) n (%)
Provider Type	
Attending	1 (25%)
Fellow	1 (25%)
MCS Coordinator	2 (50%)

Table 5. Outcomes for POCT and Lab Testing

	Meter (n =17) mean (SD) or n (%)	Lab (n = 15) mean (SD) or n (%)	*p*
Time in therapeutic window	58.3% (15.6)	50.3% (16.6)	.17
Adverse event			.15
Yes	8 (47.1%)	3 (20%)	
No	9 (52.9%)	12 (80%)	
TIA	2 (11.8%)	1 (6.6%)	1
Ischemic Stroke	2 (11.8%)	0 (0%)	.49
Pump Thrombus	1 (5.9%)	0 (0%)	1
Subarachnoid	0 (0%)	2 (13.3%)	.21
Hemorrhage	2 (11.8%)	0 (0%)	.49
GIB	1 (5.9%)	0 (0%)	1
Hemorrhagic Stroke			

Table 6. Provider Cumulative Pre-Post Test Scores

Paired Samples Test

		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	Pre_test - Post_test	-.16750	.33500	.16750	-.70056	.36556	-1.000	3	.391

Table 7. Provider Pre-Post Test Scores by Question (n=4)

	Pre-Survey *Mean*	Post-Survey *Mean*	*p*
Complications	0 (0)	50%	.18
Cost	50%	50%	1
TTR	100%	100%	1

Table 8. Cost

	POC Meter	Lab
Private Insurance	$240/year	$6/test
Medicare	$240/year	Free

Appendix A. Demographic Survey

Demographic Survey

1. What gender do you identify as:
    a. Male
    b. Female
    c. _____
    d. Prefer not to answer

2. What is your age?
    a. _____

3. Please specific your ethnicity
    a. Caucasian
    b. African-American
    c. Latino or Hispanic
    d. Asian
    e. Native American
    f. Native Hawaiian or Pacific Islander
    g. Two or More
    h. Other/Unknown
    i. Prefer not to answer

4. Which languages are you capable of speaking fluently?
    a. English
    b. Spanish
    c. Portuguese
    d. French
    e. Mandarin
    f. Arabic

g. Other
h. Prefer not to say

5. What is your New York Heart Association (NYHA) Heart Failure status?
    a. Class I - No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
    b. Class II- Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
    c. Class III - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20—100 m).Comfortable only at rest.
    d. Class IV- Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.
    e. No NYHA class listed or unable to determine.

6. Do you have a mechanical circulatory device?
    a. Heartware
    b. HeartMate II
    c. HeartMate III

Appendix B. Pre and Post Test

Point of Care INR Testing In Left Ventricular Device Patients: A Clinical Evaluation
Provider Test

1. Does point of care (POC) INR testing correlate to more thrombotic or hemorrhagic complications when compared to clinical lab INR testing?
    a. Yes
    b. No
2. Is POC INR testing in LVADs more cost effective when compared to clinical lab INR testing?
    a. Yes
    b. No
3. Do patients utilizing POC INR have a higher percentage of time in their therapeutic (TTR) window?
    a. Yes
    b. No