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CardioMEMS Heart Failure System: Keeping Patients out of the Hospital

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Introduction

It is well known that heart disease is the leading cause of death in the United States, with about 670,000 new diagnoses of congestive heart failure (CHF) each year (Suh et al., 2011). CHF results from a number of different causes, produces many different symptoms and occurs when the heart muscle cannot efficiently pump blood to the rest of the body (Suh et al., 2011). In the United States, heart failure (HF) and associated hospitalizations are leading contributors to high health care costs (Feltner et al., 2014). Up to one fourth of patients hospitalized with HF are readmitted within 30 days of discharge (Feltner et al., 2014). In an effort to reduce expenditures for the Centers for Medicare & Medicaid Services (CMS), new policies have been created to help reduce readmission rates of HF patients (Feltner et al., 2014). This has resulted in hospitals providing special HF education prior to discharge, HF coordinators, and HF clinics. In our age of technology, there have been many new innovations to help keep patients with HF out of the hospital and improve their quality of life. Some include new medications, telemonitoring, and implantable devices. The CardioMEMS HF System is a new device, recently approved by the U.S. Food and Drug Administration (FDA), which will optimistically prevent frequent hospitalizations for patients with HF (U.S. Food and Drug Administration [FDA], 2014). According to the FDA (2014), the CardioMEMS HF System monitors patient's pulmonary artery pressures (PAPs) and heart rate after a small, battery-free device is permanently implanted into the pulmonary artery. The PA pressures and trends can be remotely reviewed by the physician, who can then adjust the patient's medication regimen (FDA, 2014). Thus far, the studies related to the CardioMEMS HF System have been very promising in keeping patients with HF out of the hospital and improving his or her quality of life.

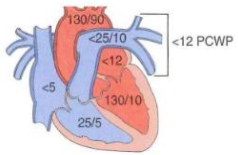

Figure 1. Normal pressures in the heart and pulmonary artery. Adapted from Lancashire & South Cumbria Cardiac Network, n.d.

Pathophysiology

When the heart, or myocardium, cannot pump a sufficient amount of blood throughout the body, for whatever reason, it is simply termed congestive heart failure (CHF) (Suh et al., 2011). However, CHF is a complex condition that involves the metabolic, neuroendocrine, and immune systems (Wrigley, Lip, & Shantsila, 2011). An abnormal heart muscle, or cardiomyopathy, can be categorized as primary or secondary, ischemic or non-ischemic, and dilated, hypertrophic, or restrictive (Frazier, Wung, Sparks, Eastwood, 2009). All of which may lead to CHF. There are two main categories of HF, systolic and diastolic. Depending on when in the cardiac cycle there is a deficiency, depends on the type of HF. The heart can have difficulties during systole, when the heart muscle contracts and ejects blood from the heart out to the lungs and body, or during diastole, when the heart is at rest and the chambers are filling with blood (Suh et al., 2011). There are additional classifications of left ventricular failure, right ventricular failure, or biventricular failure (Nicholson, 2014). It is with left-sided heart failure when fluids back up into the pulmonary system, thus increasing the PAPs.

There are many pressures within the heart, vessels, and lungs that can be measured for diagnostic purposes. As blood moves from the right ventricle into the pulmonary artery, the pressure is much lower than the blood pressure from the left ventricle into the aorta. Normal systolic pressures in the pulmonary artery are less than 25 mm Hg and normal diastolic pressures are less than 10 mm Hg (Lancashire & South Cumbria Cardiac Network). When PAPs rise, it could be caused by a number of factors, but for patients with HF, it is typically due to fluid overload. Fluid and sodium intake need to be decreased and diuretics may need to be increased by the physician. For patients with renal failure, they may need an extra dialysis treatment.

While some pathological causes of CHF may be reversible, such as infection and thyroid imbalances, many causes are not, such as hypertension and ischemic heart disease (Nicholson, 2014). Coronary artery disease (CAD), a very common cause of CHF, results in coronary vessels becoming blocked or occluded. Heart tissue becomes ischemic and progresses to infarction and necrosis of the heart tissue resulting in HF. In increased peripheral vascular resistance, or hypertension, the heart has to work harder to pump blood out of the heart. Like any muscle, the harder the muscle has to work, the larger it gets up to a certain point. Frazier et al. (2009) describes cardiac remodeling as either hypertrophy or dilation. Heart cells, or myocytes, change shape and increase in number to compensate (Frazier et al., 2009).

Perfusion is maintained by the compensatory changes of increased vasopressin, activation of the renin-angiotensin-aldosterone system, and amplified adrenergic drive (Bergamini, Cicoira, Rossi, & Vassanelli, 2009). These changes cause the kidneys to reabsorb a greater amount of water, thus increasing blood volume to increase blood pressure (Bergamini et al., 2009). However, the increase in blood volume causes the heart chambers to stretch. Along with chronic pressure overload, these neurohumoral stimuli are thought to contribute to the development of cardiac hypertrophy (Bergamini et al., 2009). However, over time these compensatory mechanisms result in negative effects seen in chronic HF (Bergamini et al., 2009). Once the myocardium stretches to the point where it cannot contract strongly, the heart fails to pump efficiently.

While there is still much research to be done, there is evidence that monocytes, inflammation, and oxidative stress play a role in the pathophysiology of HF. Wrigley et al. (2011) report that inflammatory cytokines, such as tumor necrosis factor (TNF), are released in HF and are associated with LV dysfunction, remodeling, and myocyte apoptosis. When cardiac tissue is injured, monocytes help rid the body of necrotic tissue by phagocytosis and apoptosis (Wrigley et al., 2011). As inflammation continues, oxidative stress, which results when aerobic cells produce an excessive amount of reactive oxygen species (ROS), causes cellular damage and cardiac fibrosis (Bergamini et al., 2009). When the heart tissue becomes fibrotic, or stiff, it cannot pump as forcefully. Nitric oxide is also produced which results in weakened contraction of the myocardium (Wrigley et al., 2011).

CardioMEMS HF System

When blood is not adequately pumped out of the heart, the blood volume backs up into other areas of the body, such as the lungs or periphery. When patients have left-sided heart failure, blood backs up into the pulmonary artery (PA) and lungs. This results in pulmonary edema, which causes shortness of breath and even respiratory failure. When the pressures in the PA are directly measured with the CardioMEMS HF device, clinicians can remotely monitor and proactively treat rising PAPs before patients present with symptoms related to decompensating HF (St. Jude Medical, Inc., 2014). In turn, this keeps patients from being re-admitted to the hospital for exacerbations. Dr. Abraham (2014), at Ohio State University, states that the CardioMEMS heart failure system is beneficial for patients with systolic and/or diastolic heart failure. The CHAMPION clinical trials for the CardioMEMS HF System showed a 28% reduction of hospital re-admissions after six months and a 37% reduction after a year (St. Jude Medical, Inc., 2014).

Figure 2. Antenna and wireless electronics unit. Adapted from St. Jude Medical, Inc., 2014

The CardioMEMS HF system consists of a small, battery free sensor, an antenna, and a wireless electronics unit. The sensor is permanently placed by a physician under fluoroscope into the PA via the femoral vein (St. Jude Medical, Inc., 2014). The sensor cannot be felt and will not interfere with other implanted devices, such as a pacemaker; however, as with any invasive procedure, there are rare complications that can occur (St. Jude Medical, Inc., 2014). Of note, 98.8% of patients in the clinical trial were free from complications related to the device (St. Jude Medical, Inc., 2014). Each morning the patient will take a few minutes to lay on a pillow containing the paddle-shaped antenna. The electronics unit will then read the patients PAPs and send them to a secure website that his or her doctor can access (St. Jude Medical, Inc., 2014). By directly measuring the pressures in the PA, physicians can adjust patients' medications before they develop symptoms of worsening heart failure due fluid retention (Rose & Abraham, 2014). This not only helps keep patients at home and out of the hospital, but it improves their quality of life (Rose & Abraham, 2014).

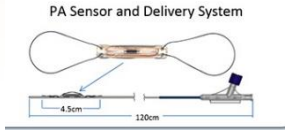

Figure 3. Adapted from St. Jude Medical, Inc., 2014

Nursing Implications

It is inevitable that nurses will care for patients with some degree of CHF. It is important for nurses to understand the pathophysiology of HF. In doing so, nurses can better educate and treat patients. In the hospital setting, nurses can screen patients for risks of re-admission and advocate for patients so they can receive available services at home (Smith, 2013). Frazier et al. (2009) stress that clinicians should update their education on genetics and genetic testing as genetic discoveries related to HF are made. Nurses play a pivotal role in the education of HF including medications, devices, diet and lifestyle changes. The more patients understand their illness, the more likely they are to better manage their disease (Falk, Ekman, Anderson, Fu, & Granger, 2013). In the case of the CardioMEMs HF System, the nurse should educate the patient on post-procedure care. Because the clinician will be adjusting the patient's medications regularly, it is important that the patient fully understands the medication(s). It is also important that nurses provide emotional support and help patients with HF cope with the loss of independence, social isolation, and fear of the impending progression of his or her HF (Falk et al., 2013).

Signs & Symptoms

Depending on the type of myocardial dysfunction and the progression of the disease results in different signs and symptoms related to HF. The New York Heart Association (NYHA) uses a four class system to classify symptoms and monitor progress (Nicholson, 2014). The CHAMPION clinical trial studied patients with class III heart failure (St. Jude Medical, Inc., 2014). Patients with class III HF have obvious limitations and excessive breathlessness, fatigue or palpitations (Nicholson, 2014). Other clinical presentations of HF include orthopnea, nocturnal cough and dyspnea, peripheral edema, bloating, loss of appetite, confusion, angina, and syncope (Nicholson, 2014). Nicholas (2014) also lists signs that someone may have HF and might include tachypnea, tachycardia, irregular pulse, wheezing, weight changes, jugular venous distention (JVD), abnormal heart sounds such as a gallop or murmur, and pleural effusions. These effects of HF are what limit patient's activities of daily living and have been found to contribute to depression and a decreased quality of life.

Conclusion

As the baby boomers continue to age, there will undoubtedly be an increase in the number of people living with CHF. While focus should remain on preventative care, education, and decreasing risk factors for developing HF, the goals of care will continue to be improving quality of life while providing cost-effective and evidence-based care (Smith, 2013). Patients with HF require frequent office and/or clinic visits for medication titration and symptom monitoring; however, disability, transportation, and cost could be barriers for compliance of these visits (Smith, 2013). Patients with the implantable CardioMEMs HF System can be monitored from the comfort of their home and optimistically decrease hospitalizations related to HF symptoms. As further research continues with medications, devices, and at the cellular level, the CardioMEMs HF System can safely improve the quality of life for patients with HF.

References

Bergamini, C., Cicoira, M., Rossi, A., & Vassanelli, C. (2009). Oxidative stress and hyperuricaemia: Pathophysiology, clinical relevance, and therapeutic implications in chronic heart failure. *European Journal of Heart Failure, 11*(5), 444-452. doi:10.1093/eurjhf/hfp042

Falk, H., Ekman, I., Anderson, R., Fu, M., & Granger, B. (2013). Older patients' experiences of heart failure-An integrative literature review. *Journal of Nursing Scholarship, 45*(3), 247-255. doi:10.1111/jnu.12025

Feltner, C., Jones, C., Cené, C., Zheng, Z., Sueta, C., Coker-Schwimmer, E., . . . Jonas, D. (2014). Transitional care interventions to prevent readmissions for persons with heart failure: A systematic review and meta-analysis. *Annals of Internal Medicine, 160*(11), 774-784. doi:10.7326/M14-0083

Frazier, L., Wung, S., Sparks, E., & Eastwood, C. (2009). Cardiovascular nursing on human genomics: What do cardiovascular nurses need to know about congestive heart failure? *Progress in Cardiovascular Nursing, 24*(3), 80-85. doi:10.1111/j.1751-7117.2009.00039.x

Lancashire & South Cumbria Cardiac Network. Normal & Abnormal Intracardiac Pressures [Powerpoint]. Retrieved from https://lane.stanford.edu/ portals/cvicu/HCP_CV_Tab_1/ Intracardiac_Pressures.pdf

Morrissey, R. P., Czer, L., & Shah, P. K. (2011). Chronic heart failure. *American Journal of Cardiovascular Drugs, 11*(3), 153-171. doi:10.2165/11592090 000000000-00000

Nicholson, C. (2014). Chronic heart failure: Pathophysiology, diagnosis and treatment. *Nursing Older People, 26*(7), 29-38. doi:10.7748/nop.26.7.29.e584

Rose, C. (Interviewer) & Abraham, W. (Interviewee). (2014, September 19) Cardiologist Dr. William Abraham Discusses CardioMEMS Heart Failure Monitoring System Which Improves Patients Quality of Life Interview [Interview transcript]. Retrieved from http://candieanderson.com/2014/09/ cardiologist-dr-william-Abraham discusses cardiomems-heart-failure monitoring-system-which-improves patients-quality-of-lifeinterview.html

References cont.

St. Jude Medical, Inc. (2014). Pulmonary Artery Pressure Monitoring. Retrieved from http://health.sjm.com/heart failure-answers/treatmentoptions/ pulmonary-artery-pressuremonitoring

Smith, A. (2013). Effect of telemonitoring on re-admission in patients with congestive heart failure. *MEDSURG Nursing, 22*(1), 39-44. Retrieved from http://ezproxy.otterbein.edu/login? url=http://search.ebscohost.com/ login.aspx?direct=true&db=rzh&AN= 20119094&site=ehost-live

Suh, M., Chen, C., Woodbridge, J., Tu, M., Kim, J., Nahapetian, A., . . . Sarrafzadeh, M. (2011). A remote patient monitoring system for congestive heart failure. *Journal of Medical Systems, 35*(5), 1165-1179. doi:10.1007/s10916-011 9733-y

U.S. Food and Drug Administration. (2014). FDA approves first implantable wireless device with remote monitoring to measure pulmonary artery pressure in certain heart failure patients [Press release]. Retrieved from http://www.fda.gov/newsevents/ newsroom/pressannouncements/ ucm399024.htm

Wrigley, B., Lip, G., & Shantsila, E. (2011). The role of monocytes and inflammation in the pathophysiology of heart failure. *European Journal of Heart Failure, 13*(11), 1161-1171. Retrieved from http://ezproxy.otterbein.edu/ login?url=http://search.ebscohost.com/login.aspx?direct=true&db=rzh&AN=2011330024&site=ehost-live

Additional Sources

www.heartfailureanswers.com

http://www.sjm.com/cardiomems

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