ACCEPTED MANUSCRIPT

Development of a Protocol for Successful Palliative Care Consultation in Population of Patients Receiving Mechanical Circulatory Support

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Abstract

Background: In 2014, Joint Commission recommended palliative care (PC) engagement in ventricular assist device (VAD) implantation as destination therapy. Limited information is available on established PC protocols in the mechanical circulatory support (MCS) population.

Measures: The goals of our PC consultation were to document advance care planning (ACP) discussions and designate a surrogate decision maker (SDM) prior to MCS implantation. A retrospective analysis compared the frequency of PC consults, ACP discussion, and SDM before and after protocol implementation.

Intervention: A protocol was developed to conduct interdisciplinary PC consultations for the MCS population.

Outcomes: The percentage of PC consults placed prior to MCS implantation increased from 11 (17.2%) pre-protocol to 56 (96.6%) post-protocol (p<0.0001), and documented SDM increased from 26 (40.6%) pre-protocol to 57 (98.3%) post protocol (p<0.0001).

Conclusion: Close PC/cardiology collaboration can substantially improve ACP discussions and SDM documentation in the MCS population. This multidisciplinary protocol facilitates successful PC consultations.

Key words: Palliative Care, Mechanical Circulatory Support, Advance Care Planning, Surrogate Decision Maker, Ventricular Assist Device

Running Title: Palliative Care consult protocol in MCS candidates

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BACKGROUND

Approximately 5.7 million Americans are currently diagnosed with heart failure with about 300,000 deaths per year. The prevalence has doubled over the last 25 years and is estimated to double again between 2030 and 2040 with the aging of the population.[1] When patients fail to respond to medical therapies, they are considered for advanced therapies such as heart transplant and mechanical circulatory support (MCS) devices. The two-year survival for continuous flow ventricular assist devices (VAD) in patients with low risk of complications has been shown to parallel that of cardiac transplantation, with patients reporting improved quality of life and functional capacity.[2] However, the majority of patients are at an increased risk of complications such as bleeding, infection, stroke, pump thrombosis, and respiratory failure amongst others.[3] These can add significant stress and symptom burden to patients and their families. Additionally, the patients getting these devices as destination therapy (DT) will face the end of life with the VAD in place. Due to the need for advance care planning (ACP) and symptom management, the Centers for Medicare and Medicaid Services and The Joint Commission recommended in 2014 that a PC representative experienced with the VAD population be part of the interdisciplinary team based on patient and family needs.[4]

Swetz et al. proposed that a preparedness plan /ACP should be incorporated as part of a PC evaluation in this population.[5] Advance care plans support care congruent to patients stated preferences.[6] However, limited information is available on established PC protocols and metrics in the MCS population. Prior to our protocol intervention, very few patients receiving MCS at our institution had an ACP and rarely was the PC team involved in their care.

We developed and implemented a collaborative protocol between the PC team and the VAD team to ensure a multidisciplinary approach and timely PC consultation for all patients

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being considered for MCS implantation. Our protocol included all patients being evaluated for MCS regardless of whether they were DT or bridge to transplant (BTT) and even included total artificial heart (TAH) patients. Because of the complex needs of this patient population, we incorporated an interdisciplinary team approach to our PC consultation. We sought to assess whether our collaborative approach resulted in a significant increase in the completion of an interdisciplinary PC consult and documentation of a surrogate decision maker (SDM).

MEASURES/ INTERVENTIONS

Intervention

On March 1, 2014, a standardized PC consultation protocol for all MCS candidates was implemented at our institution (Figure 1). Our goal was to complete an interdisciplinary PC consultation on all patients prior to MCS implantation. This protocol relied on close collaboration between heart failure specialists, cardiothoracic surgeons, and PC specialists to enable timely and effective PC evaluations. This was elemental to the success of our intervention and required active engagement in the planning stage from both teams. The clinical nurse coordinators from both the PC and cardiology teams were designated as main contact persons to ensure consistent, shared communication. We developed a routine quarterly meeting between the teams to provide ongoing feedback and review of the protocol. We also participated in the weekly interdisciplinary team discussions for patients either with implanted MCS or undergoing evaluation for the same.

Identification of Patients

The Cardiology team identifies patients being evaluated for MCS implantation and then generates an electronic medical record alert for PC consult prior to implant. The protocol includes both DT and BTT designated patients as well as TAH patients. Including both DT and

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BTT patients is advantageous, as BTT patients can experience future complications that would remove them from transplant consideration.[7]

Content of the PC Consultation

After the cardiology team enters an electronic medical record alert for PC consultation, there is direct communication between nurse coordinators on both teams to share pertinent information prior to evaluation. PC consultations incorporate visits from the interdisciplinary team which includes PC trained physicians or advanced practice nurses, PC social worker, and PC chaplain.

Goals of the PC consultation are to facilitate identification and documentation of a SDM, to assist with ACP needs, and to provide symptom-based physical, emotional, psychosocial, and spiritual support to the patient and/or their family members. For this report, ACP is defined as discussing medical care that a patient would like to receive in the future in the event the patient is unable to speak for him or herself. ACP discussions are documented in a formatted PC clinical note, and advanced directives, including the SDM document, are scanned and saved in a fixed section for advanced directive in the electronic medical record for easy access. The existing PC inpatient consulting team is primarily used as our resource, and therefore, patients are seen when admitted to the hospital often when undergoing preparation for implantation. The PC team is not always part of the early decision-making process as patients are often admitted with the intent to implant an MCS.

Our model includes an interdisciplinary and ongoing assessment by the PC clinician as well as the PC social worker and chaplain to address psychosocial and spiritual needs both before and after implantation. Visits are tailored according to the identified needs of the patient and family. In several cases, we have identified psychosocial and spiritual needs to be greater

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than the medical needs. Examples of psychosocial needs include adjustment to illness, grief over loss of independence, and caregiver support.

Our PC consultation is not just limited to a preoperative consultation. After the initial evaluation, the PC team continues to work collaboratively with the cardiac team throughout MCS workup and after MCS implantation with regular patient visits. The protocol relies on PC involvement both before and after device implantation to ensure continuity of care and is not limited to ACP alone.

Measures

A retrospective pre/post analysis was done to assess this protocol and its quality improvement impact. Chart review was performed on all patients who received MCS devices at our academic health center. The analysis included two observation periods: before the implementation of the standardized PC consultation protocol (pre-PC protocol) from January 1, 2012, to February 28, 2014, and after implementation (post-PC protocol) from March 1, 2014, to December 31, 2015. Approval was obtained from the Indiana University Institutional Review Board for future study implications.

Patient demographic characteristics were obtained from the retrospective chart review. Detailed information about involvement of the PC team was also recorded, including: presence of PC consult pre and post implantation, presence of documented SDM pre and post-MCS implantation, members of the PC team involved in the patient's care pre and post-MCS implantation, physical location of death for deceased patients, and PC team or hospice involvement at the time of death.

Statistical Analysis

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For both demographic and participant outcomes, Student's t-tests were performed for continuous variables to look for differences between groups (pre- vs. post-PCC protocol). All analytic assumptions were verified, and Wilcoxon non-parametric tests were performed when continuous variables were determined to be non-linear. For categorical variables, Fisher's Exact tests were used to determine if there was significant heterogeneity between groups, due to low cell counts. All analyses were performed using SAS v9.4 (SAS Institute, Cary, NC).

OUTCOMES

Demographics

There were 122 patients implanted with MCS devices from January 1, 2012, to December 31, 2015, with 64 pre-protocol and 58 post–protocol patients (Table 1). The group prior to protocol implementation included more women (39.1% v. 20.7%, p=0.0315) and small differences in marital status (p=0.0497). The two groups were similar in other demographics. Mean age was 57.73±12.85 years and 54.86±12.85 years for pre- and post-protocol groups, respectively. Hospital lengths of stay were skewed, and so are given with median (range), and are 30.6 days (13.2-148.9) and 30.1 days (0.4-95.0), respectively.

Protocol Results

The total overall percentage of PC consults placed prior to MCS implantation was 54.9% (67) from 2012 to 2015. The percentage of PC consults placed prior to MCS implantation increased from 17.2 % (11) pre-protocol to 96.6% (56) post-protocol ($p<0.0001$), and documented SDM increased 40.6% (26) pre-protocol to 98.3% (57) post-protocol ($p<0.0001$; Table 1). Of note, the proportion of documents completed by the PC team (versus previously completed) did not change (80.8% v/ 79.0%. p=0.8487) as shown in Table 1.

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The use of the multidisciplinary PC team members in the MCS population before and after implant increased across all disciplines post-protocol ($p<0.0001$). However, the distribution of team member use before and after implant was found not to be statistically different ($p<0.10$), suggesting that team members continued their involvement post implant (Table 1).

In the total patient sample ($n=122$), 31 patients (25.4%) were deceased as of data collection. There were no statistical differences in the use of hospital-based palliative care ($p=0.2930$) or hospice care ($p=0.2955$) at the end of life between the pre-protocol ($n=19$; 29.7%) and post-protocol ($n=12$; 20.7%) samples. The majority of patients both pre- protocol (84.2%) and post- protocol (83.3%) died in the hospital. Only two patients both pre- and post- protocol died at home ($p=0.6547$).

CONCLUSIONS

We developed a collaborative protocol between the PC and cardiology teams to include all patients undergoing evaluation for MCS. This was associated with near 100% rate of PC evaluations completed prior to MCS implantation and a substantial increase in the number of patients with a documented SDM. The Joint Commission has recommended the involvement of PC evaluation for DT VAD implants.[4] However, our protocol was designed to include all MCS patients given the knowledge that BTT patients have similar needs for ACP and may get removed from the transplant list based on complications or clinical changes.[7]

We used our electronic medical record system effectively to generate an automated PC consult trigger when a patient was identified. This guaranteed notification of the PC consultation request for the MCS population. The electronic medical record was also used for documentation and storage of ACP/SDM documents in a defined location to ensure easy and consistent accessibility. We had a standardized structure for documenting the ACP that was influenced by

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the preparedness plan as suggested by Swetz et al.[5] The basic requisite was to document patient

preferences for ACP, name and contact information for SDM, and any symptoms needing to be

addressed. SDM documentation was used as a metric for our protocol success, because the goal

of ACP is to include patients in shared decision-making and provide care in accordance with

their preferences. Identifying a SDM is an important step to safeguard that patient wishes for

care are honored.[8,9]

While undergoing MCS implantation, patients are under anesthesia for a significant time

period and on mechanical ventilation post-operatively. During this time period, patients are

unable to speak for themselves. Patients may suffer minor or major complications leaving them

incapacitated and unable to have complex medical discussions. Surrogacy laws vary by state, and

in Indiana, the laws are particularly complex, with multiple family members having equal

authority in decision making. Patients are often unaware of these laws. Even with a well-

developed ACP, surrogates are needed to interpret patient preferences and translate them into

concrete medical decisions. By identifying a legal SDM and including the SDM in the ACP

discussions, the goal is to ensure the patient's wishes are honored in such an event.

The development of this protocol identified a growing need for outpatient follow-up to

provide symptom management and ongoing palliative support. Based on these observations an

outpatient component to the collaboration has been established.

While the Joint Commission recommends a PC representative who has experience with

the VAD patient population be part of the interdisciplinary team, we provided a

multidimensional approach of care to the patients across the spectrum including needs beyond

ACP. We were additionally able to provide this service to all patients under evaluation for MCS.

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Challenges were identified in the implementation of the protocol. One challenge was how to allocate resources from an already busy service towards this specialized group of patients. We limited this challenge by tailoring visits based on needs after the first evaluation and by frequent chart reviews and close collaboration with the primary cardiology team and other staff. Also, by utilizing our multidisciplinary approach effectively, we were able to limit the impact of this challenge on our PC service. Limited time constraints within a hospital stay during MCS workup added to the overwhelming amount of new staff members introduced to the patient and their family was also a challenge. An addition of an outpatient clinic for earlier counseling and decision making was identified as beneficial. Future studies could replicate the protocol at multiple centers using similar metrics for success. Another area to explore is how PC can benefit patients through psychosocial and symptom support during the course of MCS implantation. A similar model can be looked at in patients with serious illness who are considering discrete interventions such as renal replacement therapy, organ transplant, and any major preoperative evaluations. Future research could also ascertain protocol impact on a patient's end of life experience and care including the use of PC and hospice services.

Limitations

The observations presented are from a relatively small cohort limited to one institution, and as such would need to be validated by implementation in different settings. Additionally, the data was retrospective and based on chart review, and ongoing evaluation of this protocol would be beneficial. The mortality numbers in the given cohort were not large enough to allow adequate assessment of benefits the PC team provided in end of life care. Also, the cohort is too small to allow comparisons between BTT and DT patients.

Conclusions

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The results demonstrated that at a single institution, an automated PC consult protocol and interdisciplinary consult approach for MCS candidates results in completion of a PC consult and successful documentation of a SDM with a high success rate. Close collaboration and a multidisciplinary approach were found to be critical and fundamental to the success of this protocol. An integral element of the protocol was the communication between the team clinical nurse coordinators. An automated consultation trigger via the electronic medical record along with documentation within the electronic medical record proved beneficial. The desired outcome from the multidisciplinary approach was to provide care concordant with stated goals, reduced symptom burden, and to improve SDM education and documentation.

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Table 1
Patient Demographics and Results

Patient Characteristics & Results	Pre-PC Protocol (*n*=64)		Post-PC Protocol (*n*=58)		Total (*n* = 122)		*P*-values[1]
	n	(%)	*n*	(%)	*n*	(%)	
Age (Range, Mean)		24-75, 57.73		26-78, 54.86		24-78, 56.37	0.2200
Hospital Length of Stay (Range, Mean)		13.2-148.9, 34.6		0.4-95, 34.2		0.4-148.9, 34.43	0.9837
Sex							0.0315
Male	39	(60.9)	46	(79.3)	85	(69.7)	
Female	25	(39.1)	12	(20.7)	37	(30.3)	
Race							0.6771
Caucasian	49	(76.6)	46	(79.3)	95	(77.9)	
African American	14	(21.9)	9	(15.5)	23	(18.9)	
Native Hawaiian or Pacific Islander	0	(0)	1	(1.7)	1	(0.8)	
Hispanic	0	(0)	1	(1.7)	1	(0.8)	
Unknown	1	(1.6)	1	(1.7)	2	(1.6)	
Education							0.8551
Some High School	5	(7.9)	7	(12.5)	12	(9.8)	
High School/GED	32	(50.8)	26	(46.4)	8	(6.6)	
<4 years College	18	(28.6)	17	(30.4)	19	(15.6)	
College/Graduate Degree	8	(12.7)	6	(10.7)	11	(9.0)	
Marital Status							0.0497
Single	2	(3.1)	10	(17.2)	12	(9.8)	
Significant Other	4	(6.3)	5	(8.6)	9	(7.4)	
Married	45	(70.3)	35	(60.3)	80	(65.6)	
Separated	2	(3.1)	2	(3.4)	4	(3.3)	
Divorced	7	(10.9)	6	(10.3)	13	(10.7)	
Widowed	4	(6.3)	0	(0)	4	(3.3)	
Type of Therapy							0.8543
BTT	25	(39.1)	24	(41.4)	49	(40.2)	
DT	39	(60.9)	34	(58.6)	73	(59.8)	
MCS Implanted							0.0091
Heartware	12	(18.8)	23	(39.7)	35	(28.7)	
HeartMateII	51	(79.7)	32	(55.2)	83	(68.0)	
HeartMateIII	0	(0)	2	(3.4)	2	(1.6)	
TAH	1	(1.6)	1	(1.7)	2	(1.6)	
PC Consult Prior to Implant	11	(17.2)	56	(96.6)	67	(54.9)	<0.0001
SDM Documented Prior to Implant	26	(40.6)	57	(98.3)	83	(68.0)	<0.0001
SDM Documents							0.8487
Completed with PC Team	21	(80.8)	45	(79.0)	66	(79.5)	
Pre-existing Documents	5	(19.2)	12	(21.1)	17	(20.5)	
PC Team Member Involvement[2]							<0.10
Before MCS Implant							
Physicians	10	(15.6)	41	(70.7)	51	(41.8)	<0.0001
Advanced Practice Nurses	6	(9.4)	27	(46.6)	33	(27.0)	<0.0001
Social Work	9	(14.1)	44	(75.9)	53	(43.4)	<0.0001
Chaplain	7	(10.9)	35	(60.3)	42	(34.4)	<0.0001
After MCS Implant							
Physicians	5	(7.8)	33	(56.9)	38	(31.1)	<0.0001
Advance Practice Nurses	5	(7.8)	26	(44.8)	31	(25.4)	<0.0001
Social Work	9	(14.1)	50	(86.2)	59	(48.4)	<0.0001
Chaplain	7	(10.9)	35	(60.3)	42	(34.4)	<0.0001

[1]*P*-values are from Fisher's Exact tests for categorical variables, Student's t-test for age, Wilcoxon non-parametric test for LOS
[2]P-value from non-parametric two-sample Kolmogorov-Smirnov test

Figure 1 Palliative Care and Cardiology Protocol Diagram