Medical Product Safety Network (MedSun)
Small Sample Survey

Topic: Experience with SynCardia Temporary Total Artificial Heart
(SynCardia TAH-t)
And Associated Circulatory Support System (CSS) and Companion 2 (C2) Drivers

October 2016

Introduction

The SynCardia Temporary Total Artificial Heart (SynCardia TAH-t System) functions as a bridge to a heart transplant in a small population of heart failure patients with severe bi-ventricular failure and is also used for a small number of patients for whom heart transplant is not an option. In addition to the C2 Driver System and the CSS Console, a third pneumatic driver system, the SynCardia Freedom Driver System, is also available to power the SynCardia TAH-t. The Freedom Driver System is portable and can be used outside of the hospital, allowing some TAH-t patients (e.g., those who are stable enough and have substantial support from a care partner) to return home while on the device. The Freedom Driver System was not the focus of the data collection described below.

On June 15, 2015, FDA posted a letter informing the health care community that they had received preliminary post-approval study information suggesting a higher mortality rate for a subgroup of patients requiring pre-implant circulatory rescue interventions when using SynCardia's TAH-t C2 Driver System as compared to the previous generation driver, the Circulatory Support System (CSS) Console.
During the time since the 2015 notice, FDA received additional interim post-approval study results indicating a higher risk of neurological adverse events for patients supported by the C2 Driver System compared to patients supported by the CSS Console and obtained updated results regarding the mortality rate associated with the C2 Driver System. As part of their review of recent information, FDA specialists wanted to learn from hospitals in FDA's Medical Product Safety Network (known as MedSun) about their experience with SynCardia TAH-t and the C2 and CSS consoles using a brief questionnaire.

FDA posted an alert with safety information concerning issues with the SynCardia TAH-t and its drivers on October 26, 2016. The survey responses from almost all of the sites contacted for this survey had been received by that time.

Methodology

A total of 20 hospitals that participate in FDA's Medical Product Safety Network (MedSun) were selected for survey recruitment and contacted by email. The selection was based on their history with the use of the SynCardia TAH-t according to available information. A short questionnaire was sent to the sites and could be filled out by the physician leader of the Cardiac Implant Center and/or others such as surgeons with experience implanting the Syncardia TAH-t, nurses or nurse practitioners who care for the patients with these devices, the VAD Coordinator or Study Coordinator, or members of the Mechanical Circulatory Support (MCS) Team.

From late September to late October 2016, 13 sites responded to the MedSun questionnaire. A 14th site that was contacted that had not implanted the SynCardia TAH-t, and they provided information about their care for a patient who had the SynCardia TAH-t artificial heart implanted at one of the other hospitals in the survey.

The results below are for the 13 sites that indicated that they had used the SynCardia TAH-t. The hospitals that responded were a mix of university-based and other acute care hospitals with heart transplant centers.

Overview of Responses:

Clinical Experience of the Respondents:

For 4 hospitals that responded, the respondents were surgeons who had implanted the artificial heart (either the lead surgeon for the cardiac center or other surgeons). For the other 9 sites, the respondents were generally members of the members of the Mechanical Circulatory Support Team (such as nurses or nurse practitioners, engineers or physicians' assistants).

Two healthcare professionals responded for certain sites. For 3 hospitals, both a surgeon who had implanted at least one SynCardia TAH-t and either the VAD Coordinator or a Nurse Practitioner shared their perspectives by answering the survey questions. When more than one person responded, their responses were generally quite similar.

Current Use of the SynCardia TAH-t and the CSS and C2 Drivers:

Although all 13 of the hospitals that responded to the survey had used the SynCardia TAH-t at least once, 4 of them had not implanted it in the last year and another 4 said they no longer use the product at all. One of these sites indicated they had stopped using it three years ago.

Of the 9 remaining hospitals that indicated they currently use the SynCardia TAH-t (or would use it if the need arose), information about the drivers they had was as follows:

1/3 had both the CSS and the newer C2 driver.

1/3 had the C2 driver but not the CSS driver

1/3 had the CSS driver but not the C2 driver

The CSS is the older, heavier driver (400 pounds), whereas the C2 is newer and smaller (40 pounds). (The Freedom Driver is the newest and by far the lightest, at 14 pounds, of the 3 types of SynCardia drivers for the TAH-t; the Freedom Driver may be used by some patients at home when they no longer need to be dependent on one of the other two larger drivers and they have the required level of 24/7 care from family members or others.) Although some sites mentioned their use of the Freedom Driver for patients who met the criteria for transfer to that driver, this summary is limited to information about the C2 and CSS drivers, which were the subject of this survey.

Several sites indicated that the availability of the drivers (from the manufacturer, SynCardia) determined which ones they used. Those that had both drivers used the CSS most frequently immediately after the SynCardia-TAH-t had been implanted, and in some cases they would change drivers if the need arose.

As mentioned earlier, respondents from 4 sites said that they have the capability to implant the SynCardia TAH-t but have not done so in the last year. The sites that had implanted the SynCardia TAH-t in the last year implanted them fairly infrequently, as shown below:

Implants in the Last Year	**Hospitals that Said They Currently Implant the SynCardia TAH-t**
0	4 (0 Implants)
1	2 (2 Implants)
2	2 (4 Implants)
7	1 (7 Implants)
Total Implanted in the Last Year:	**13 Implants from 9 Hospitals that Currently Implant**

Comparisons of the CSS and the C2 Drivers:

Although most sites had experience with only the C2 or the CSS, a respondent from one of the 3 sites with experience with both commented as follows: "The C2 (is) generally more reliable in terms of pneumatics, consistent behavior and battery life. CSS, probably due to age and extensive use, has high variable reliability." Another respondent indicated, "We prefer C2 for reliability reasons, for lack of need to find a source to fill the air tanks, and for increased patient mobility and ease of staff use…"

Those who favored the CSS said the following: "We have only used the CSS in OR and are comfortable with this driver. We wanted to gain more clinical experience with the C2 driver

before we started using it in the OR." This comment is from a different hospital that uses the CSS: "We have chosen not to use the C2 (due to) inability to hear alarms outside the patient's room."

Some sites were open to moving towards use of the C2 as the initial post-implant driver: "As we gain comfort with the C2 device we will likely use that one as it allows individual vacuum control for the independent sides of the heart."

With regard to the post-approval study information suggesting a higher mortality rate for a subgroup of patients requiring pre-implant circulatory rescue interventions when using SynCardia's TAH-t C2 Driver System as compared to the previous generation driver (i.e., the CSS driver) and the more recent information from that study indicating a higher risk of neurological adverse events for patients supported by the C2 Driver System compared to patients supported by the CSS Console, some information from the respondents may be relevant. This small survey indicates that two-thirds of the sites that used the SynCardia TAH-t generally had access to either the CSS or the C2 but not both. Some sites that were experienced with the CSS chose not to use the C2 at this time. In addition, one respondent noted what he saw as differences in the amount of training SynCardia had provided to the more recent users of the SynCardia TAH-t, and one site using the CSS indicated they had been reluctant to use the C2 because of difficulty hearing the C2 alarms outside the patient's room.

Those respondents who indicated they had used both the CSS and the C2 said that they knew of no reasons for difference in occurrences of adverse events for the two drivers. In addition, they mentioned some advantages they thought the C2 offered (such as ability to adjust the vacuum for each independent side of the heart and the mobility of the C2).

Summary

The respondents to this survey provided detailed information for FDA's ongoing research into the SynCardia TAH-t and its associated drivers. Surgeons and others indicated their experience with using these products, including availability issues that determined which drivers were used with their patients, what they saw as the advantages and disadvantages of use of each driver for patients and clinicians, and the issues that they thought needed to be addressed to make the products safer and/or more effective. They provided comments about the specific drivers that they were familiar with (C2 and/or CSS). In addition, they provided information about discontinuation of using the SynCardia TAH-t at some hospitals in recent years.

With regard to the information FDA has received through results of the post-approval study for the drivers, the respondents said that they did not know of any reasons for differences in adverse outcomes for patients who used the C2 as compared with the CSS driver. However, one respondent did provide information about what he saw as less comprehensive training being provided to newer users of the SynCardia TAH-t, which may include sites that use primarily if not exclusively the newer C2 driver. Some sites that were experienced with the CSS said they

had chosen not to use the C2 yet, while some C2 users provided information about what they saw as advantages of the C2.

Survey Limitations

Although the findings add to FDA's knowledge about the SynCardia TAH-t and its drivers, there are several limitations to the survey methodology. These include the small convenience sample of respondents and the challenge with obtaining specific product information from hospitals. In view of these limitations, the respondents' perspectives may not represent the perspectives of all device users.

Therefore, these findings represent only one piece of information. No conclusions can be made based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, clinical trials, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

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Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.