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Investigating the effect of integrated medical technologies on the instances of heart transplants through a statistical data analysis

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Abstract

Heart transplants behave as a vital procedure for patients with forms of fatal heart failure, however, with growing demand, and a significant number of waitlist candidates, medical technologies pose a viable option to address the instances of transplants annually. Through targeting procedural efficacy and quality, technologies such as ventricular assist devices and the total artificial heart, demonstrate the potential to bring about a transformative impact on the heart transplantation clinical results. This analysis investigates the correlation between medical technologies and the number of heart transplants annually, through the examination of two, three, four, and five significant years throughout the history of cardiac medical technology. This data is inspected from lenses including national transplantation and state-by-state data, and concludes that the impact of the integration of these technologies is statistically insignificant.

Keywords

Heart transplant, Medical technology, Heart failure, Population data, Annual heart transplants, Impact of medical technology, Integration of medical technology, Medical devices, Product life cycle

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Introduction

To date, 932,089 heart transplants have occurred nationally in the United States (1), serving as a vital procedure to patients suffering from conditions including end-stage heart failure, such as congestive heart failure (2), arrhythmia and additional irregularities within heartbeat rhythm and patterns, and forms of cardiomyopathy (3). The rate of annual heart transplants has demonstrated a significant increase from the 12,623 procedures performed nationally in 1988 (1), to the current 2022 figure of 42,888 (1), exemplifying the indispensability and increasing necessity for this procedure. The growing challenge of both efficacy and number of heart transplants remains prevalent; with over 3,411 heart transplant candidates on the waiting list for the procedure nationally, and a long-term survival rate ranging from 70% to 82% (4). Medical technology has demonstrated the potential to improve both instances of procedures through catalyzing efficacy, using medical solutions, hardware, and devices. This paper aims to investigate the impact of integrated medical technologies related to heart conditions on the number of annual procedural occurrences, specifically through the analysis of three significant years for the integration of medical technologies (1992, 2010, and 2014). 1992 served as a crucial year for technologies within heart transplantation - both through treatments and devices. Significant hardware was trialed and integrated in 1992, as the ventricular assist device (VAD) conveyed success in long-term survival rates among transplantees and patient survival (6). Furthermore, beginning in 1992, mechanical ventricular assistance devices, such as the Abiomed BVS 5000 (manufactured by ABIOMED, Inc., Danvers, MA), successfully assisted with biventricular support and survival to device explant and transplant. 2010 acted as a second crucial year for medical technology developments; starting in 2010, 98% of all FDA-verified VADs had a continuous flow function, demonstrating the prioritization of performance in these devices (7). 2014 also served as an essential year for the integration of medical technology, most notably, the advancements made within total artificial heart (TAH) research. Specifically, the SynCardia TAH (manufactured by SynCardia Systems, LLC Tucson, AZ, USA) is a leading model and the only FDA approved TAH globally. This device is pneumatically-centered, and dual-chambered, and has obtained over 1000 implantations as of 2014 (8). Additionally in 2014, left ventricular assist devices (LVADs) proved to assist in patient survival pre-transplant, with a 55% reduction in mortality (9).

Materials and Methods

The data for the number of heart transplants was sourced from the Organ Procurement and Transplantation Network (OPTN) (1). Population data is derived from the U.S. Census Bureau. These datasets represented the amount of heart transplants nationally and the number of transplants per state from 1988 to 2022. To determine the relationship between the instances of transplants and the integration of related medical technology, both one-tailed and two-tailed t-tests were conducted for the number of national transplants, and additionally through state-by-state data (to analyze results both as a whole and on a more granular level), using MATLAB.

National data was calculated through the use of both one tailed and two-tailed t-tests to determine significance. The percent change, adjusted for population and calculated between the number of transplants occurring year over year, was calculated through Microsoft Excel. As the national number of transplants and number of those awaiting a transplant looked at the data less granularly and demonstrated nationwide trends, a two-tailed t-test (assuming equal variances) was utilized to find the influence of medical technologies over the span of two, three, and five years before and after, to legitimately gauge a sense of impact. One year was not utilized as there is risk of a single data point being misleading. Four years was not analyzed as there would be overlap between the selected years. The selected dates which were critical for the implementation of new medical technology were 1992, 2010, and 2014. For example, 2014 was only measured over the two and three year period as it is chronologically close to 2010. The degree of effect was measured through if the p-value was greater than 0.05, and was calculated through finding the degree of freedom (DF) and t-statistic.

The relationship between the number of transplants state-by-state and medical technology was calculated through a one-tailed t-test for both transplants per capita and percent change year over year, to calculate the p-value. This number, if smaller than 0.05, demonstrated a noticeable change in the number of transplants one year before and after the integration of a specific significant medical technology. In both cases, if the p-value was greater than 0.05, the data could not support the claim that the medical technology had a direct impact on the number of annual heart transplants, therefore proving a lack of relationship between both.

Results

In this analysis, population-level data were analyzed to investigate any relationship between the integration of new medical technologies and the instances of annual heart transplants. The data used for this study included national transplantation data and state-by-state transplantation data, obtained from OPTN to examine relationships from both an expansive and granular level. Nationally, important dates for breakthroughs within cardiac medical technologies were used, and a two-tailed independent t-test was conducted to observe any statistical significance in the number of heart transplants between the years before and after integration of each technology. This analysis tested significance by averaging the annual number of transplantations annually over one, two, and three year intervals, and then applied a t-test to these averages before and after the significant dates (1992, 2010, and 2014). In 1992, we observed no statistical significance in the number of transplantations before and after the introduction of VADs. The national number of transplants averaged over two years, yielded ($t(2) = 0.681$, $p = 0.566$), demonstrating no statistical significance at the national level, and (t(74) = -0.553, p = 0.581) at the state-by-state level. The medical technologies implemented in 1992 were also averaged over a 3 year interval period, where (t(4) = 0.708, p = 0.517) calculated for the national transplantation data, and (t(70) = -0.163, p = 0.870) for the state-by-state data results. This indicated no statistical significance in the relationship between the integration of medical technology and instances of heart transplants.

In 2010, there was no statistical impact at the national level at a two year interval, as (t(2) = -0.696, p = 0.558), and (t(70) = 1.281, p = 0.204) at a state-by-state level. Similarly, the data demonstrated no impact nationally, as (t(4) = -1.100, p = 0.332) in national transplantations, and (t(70) = -0.217, p = 0.828) state-by-state over a three year period. This was also tested over a four year period, where (t(6) = -1.338, p = 0.229), which indicated no correlation over this period nationally.

In 2014, it was calculated that (t(2) = -0.408, p = 0.722) using the national dataset and (t(71) = -1.212, p = 0.229) in state-by-state data, indicating no statistical significance over a two year period. Nationally, data provided (t(4) = -1.544, p = 0.917), and state-by-state data that (t(68) = -0.691, p = 0.491) indicating no statistical significance before and after the integration of the SynCardia total artificial heart, and left ventricular assistance devices (LVADs) over a three year period. Figure 1 provides a summary of the results and demonstrates a lack of correlation between medical technology and the number of national transplantations and state-by-state transplantations, which is corroborated in Figure 2.

Overall, figure 3 shows a holistic overview of the relationship between year (ranging from 1988 to 2022 in 5-year intervals), and the number of heart transplants, adjusted per million people. No clear correlation is shown, especially within the key years of 1992, 2010, and 2014. While between 1993 and 1997, after the implementation of technology in 1992, there was an increase from 7.8 to 8.7 heart transplantations per million people, this number illustrates no long-term effect, as between 1998 and 2002, the number of transplantations per million people declined to 7.9. Regarding the integration of technology in 2010 and 2014, there is an increase shown, however it is probable that this was not connected or correlated to medical technology, as seen in the statistical analysis of two year and three year periods for both of these years. The general trend seen over time from 1998 to 2022, especially between the years of 2008 to 2022, was a growing increase in the number of transplants per million people.

	1992	
Number of years	Two	Three
National Results	($t(2) = 0.681$, $p = 0.566$)	($t(4) = 0.708$, $p = 0.517$)
State-by-State results	($t(74) = -0.553$, $p = 0.581$)	($t(74) = 0.233$, $p = 0.816$)
Statistical Significance (where $p < 0.05$)	No statistical significance	No statistical significance

	2010	
Number of years	Two	Three
National Results	($t(2) = -0.696$, $p = 0.558$)	($t(4) = -1.100$, $p = 0.332$)
State-by-State results	($t(70) = 1.281$, $p = 0.204$)	($t(71) = -0.217$, $p = 0.828$)
Statistical Significance (where $p < 0.05$)	No statistical significance	No statistical significance

	2014	
Number of years	Two	Three
National Results	($t(2) = -0.408$, $p = 0.722$)	($t(4) = -1.544$, $p = 0.917$)
State-by-State results	($t(71) = -1.212$, $p = 0.229$)	($t(70) = -0.163$, $p = 0.870$)
Statistical Significance (where $p < 0.05$)	No statistical significance	No statistical significance

Figure 1: Relationship between the integration of new medical technologies and the instances of annual heart transplants for three selected years (± 2 and ± 3 year range)

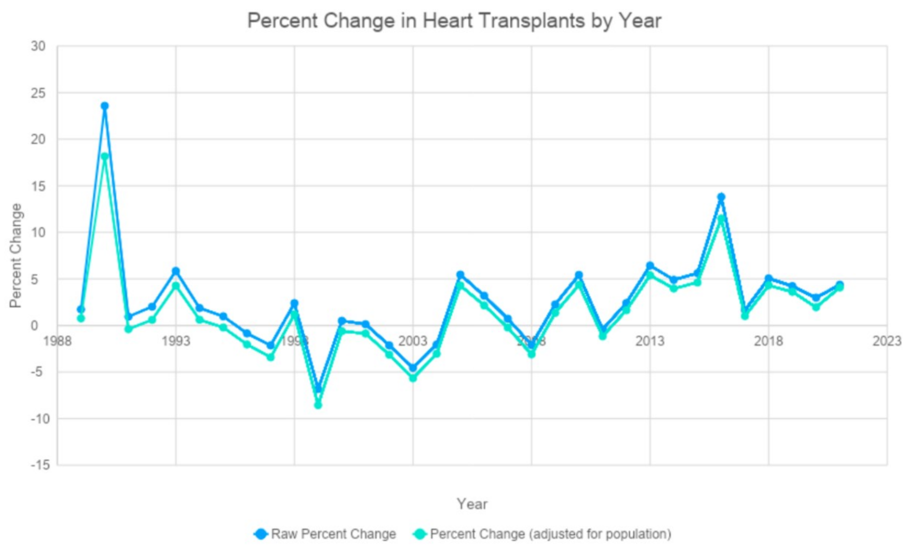

Figure 2: Percent change in heart transplants by year.

Years	Heart Transplantations per million people
1988 - 1992	7.8142
1993 - 1997	8.7424
1998 - 2002	7.8732
2003 - 2007	7.1692
2008 - 2012	7.3782
2013 - 2017	8.9888
2018 - 2022	11.224

Figure 3: Heart transplants per million persons. Digits beyond the 10^{th} place are not significant.

Discussion

The implementation of some medical technologies do have an effect on the volume of procedures conducted amongst specific procedures. For example, robotic surgical technology in prostatectomies on a granular state-by-state level - hospitals in Wisconsin without the technology were demonstrated to have a quarterly mean of 4.5 in 2002 and 3.1 in 2007 in terms of procedural instances, whereas hospitals which utilized the technology had a quarterly mean of 16.5 in 2002 and 24.8 in 2007 (10).

A potential explanation for the lack of relationship between the instances of heart transplants and the integration of new medical technology is that of confounders within the data used. The established dataset accounted for all potential explanations for the number of heart transplants per year, while the singular controlled variable in this analysis was the population growth annually (through looking at both rates per national and state-by-state population amounts). Extraneous variables and reasonings in the specific selected years other than medical technologies, population data, and the instances of heart transplants may have affected the results of the analysis if significant. For example, the lack of consistency across all states or regions in the integration of specific medical technologies nationally, may have factored into a lack of a correlation between the integration of technologies and instances of transplants. Specifically, the SynCardia total artificial heart is only integrated into hospitals in 14 states (11), potentially impacting the results for national transplantation data. Furthermore, patient consent and comfort remains a prominent issue, hindering the growth of the spread in integration of medical technologies (12). Socioeconomic barriers, public perception of specific technologies, and patients conducting a proper amount of review of the device remain crucial factors of consideration during the implementation of these technologies during procedures (13).

A secondary potential reasoning for the lack of a relationship between instances of heart transplants and the integration of new medical technology is that of cost uncertainty and barriers. This could potentially hinder systems and institutions, such as hospitals, conducting heart transplants from fully implementing medical technologies. For example, with the total artificial heart (TAH), the uncertainty between manufacturers of the device and healthcare providers (providers and payers), operating costs, and other factors such as the market, hinder the true performance of the TAH. In a study conducted between a novel TAH and the SynCardia TAH, willingness to pay and return on investments among providers and buyers was demonstrated to be low, including high societal costs and risks associated (14). This poses the need for sustainable communication throughout the product life cycle, demonstrates uncertainty within the system for purchasing and distributing high-risk devices, and additionally the high costs surrounding novel devices. In conclusion, especially within institutions, medical technologies that demonstrate efficacy but are not cost effective may have not received widespread integration.

The accessibility and availability of hearts from donors may have also been the reason for the lack of correlation between medical technologies and the instances of heart transplants. Compared to other organs available for transplantation, the heart remains one of the organs with the smallest transplant pools. For example, there have been over 553,905 kidney transplants (15), 205,102 liver transplants (16), but 89,342 heart transplants (1) as of 2022. While this is due to the fact that these organs are in higher demand due to the needs of patients eligible (such as disease and other conditions), cost of the actual procedure poses a significant factor. For example, the cost of a kidney transplant is 3/4 the cost of a heart transplant (17). This demonstrates that potentially, the variation in heart transplants may have been due to economic factors (both extraneous and known) - which in turn, could have caused changes in the number of transplants per year. For example, the national poverty level between 2009 and 2010 increased by 2.2 million nationally; an incrase of 0.6 percentage points (18). States with the most citizens below the poverty line (16% or more) experienced the most fluctuation between these periods - California, Ohio, and Tennessee all demonstrated a decrease in transplants between 2009 and 2010 (1).

Conclusion

No correlation was found between (the advancement of) medical technologies and the number of heart transplants performed annually, when examined for the cardiac technological transformative years of 1992, 2010 and 2014. The number of heart transplants were compared for two and three years pre and post transformative years at the national and state levels. The impact of the integration of these cardiac transformative technologies on the number of cardiac transplants was found to be statistically insignificant; i.e. major advancements in cardiac technology did not result in a larger number of cardiac transplants in the two or three years prior to 1992 (2010, 2014) when compared with the two or three years following 1992 (2010, 2014).

References

1. Organ Procurement and Transplantation Network National Heart Transplantation Data. (1988). https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.

2. Alraies, M. C., & Eckman, P. (2014). *Adult heart transplant: Indications and outcomes*. Journal of thoracic disease. 6 (8), 1120-1128. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4133547/

3. Zaidi, A. R., Zaidi, A., Vaitkus, P. T. (2007). *Outcome of heart transplantation in patients with sarcoid cardiomyopathy*. The Journal of Heart and Lung Transplantation. 26 (7), 714-717. https://www.sciencedirect.com/science/article/abs/pii/S1053249807003695

4. Suarez-Pierre, A., Lui, C., Zhou, X., Fraser, C. D., Ferrigno, A. S., Etchill, E., et. al. (2020). *Conditional survival in heart transplantation: An Organ Procurement and transplantation network database analysis*. The Annals of Thoracic Surgery. 110 (4), 1339-1347. https://www.sciencedirect.com/science/article/abs/pii/S0003497520303647

5. Merigan, T. C., Renlund, D. G., Keay, S., Bristow, M. R., Starnes, V., O'Connell, J. B., et. al. (1992). *A controlled trial of ganciclovir to prevent cytomegalovirus disease after heart transplantation*. New England Journal of Medicine, 326 (18), 1182–1186. https://doi.org/10.1056/nejm199204303261803

6. Reedy, J. E., Pennington, G. E., Miller, L. W., McBride, L. R., Lohmann, D. P., Noedel, N. R., & Swartz, M. T. (1992). *Status I heart transplant patients: Conventional versus ventricular assist device support*. The Journal of heart and lung transplantation, 11 (2 pt. 1), 246-252. https://pubmed.ncbi.nlm.nih.gov/1576129/

7. Stewart, G . C, Mehra, M . R. (2014). *A history of devices as an alternative to heart transplantation*. Heart Failure Clinics. 10 (1), S1-S12. https://www.sciencedirect.com/science/article/abs/pii/S1551713613000809?via%3Dihub

8. Torregrossa, G., Morshuis, M., Varghese, R., Hosseinian, L., Vida, V., Tarzia, V., et. al. (2014). *Results with SynCardia Total Artificial Heart Beyond 1 Year*. ASAIO journal (American Society for Artificial Internal Organs). 60 (6), 626-634. https://pubmed.ncbi.nlm.nih.gov/25158888/

9. Holley, C. T., Harvey, L., & John, R. (2014). *Left ventricular assist devices as a bridge to cardiac transplantation*. Journal of thoracic disease. 6 (8), 1110-1119. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4133552/

10. Neuner, J. M., See, W. A., Pezzin, L. E., Tarima, S., Nattinger A. B., (2012). *The Association of Robotic Surgical Technology and Hospital Prostatectomy Volumes.* American Cancer Society Journals , 118 (2), 371-377. https://doi.org/10.1002/cncr.26271

11. *The Syncardia Temporary Total Artificial Heart*. SynCardia. (n.d.). https://syncardia.com/

12. Raza, F., & Neuberger, J. (2022). *Consent in organ transplantation: Putting legal obligations and guidelines into practice*. BMC medical ethics, 23 (1), 69. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9255499/

13. Schiedermayer, R. S., & Shapiro, D. L. (1989). *The artificial heart as a bridge to transplant: Ethical and legal issues at the bedside*. The Journal of Heart transplantation. 8 (6), 471-473. https://pubmed.ncbi.nlm.nih.gov/2614548/

14. Federici, C., & Pecchia, L. (2022). *Exploring the misalignment on the value of further research between payers and manufacturers. A case study on a novel total artificial heart.* Health Economics, 31 (S1), 98–115. https://doi.org/10.1002/hec.4520

15. Organ Procurement and Transplantation Network National Kidney Transplantation Data. (1988). https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.

16. Organ Procurement and Transplantation Network National Liver Transplantation Data. (1988). https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.

17. Miller, L. W., Guglin, M., & Rogers, J. (2013). *Cost of ventricular assist devices.* Circulation, 127 (6), 743-748. https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.112.139824

18. Poverty: 2014 and 2015 - Census.gov. (n.d.- b). https://www.census.gov/content/dam/Census/library/publications/2016/acs/acsbr15-01.pdf