Graphical Abstract

Comparative Life Cycle Assessment of Single-Use Cardiopulmonary Bypass Devices

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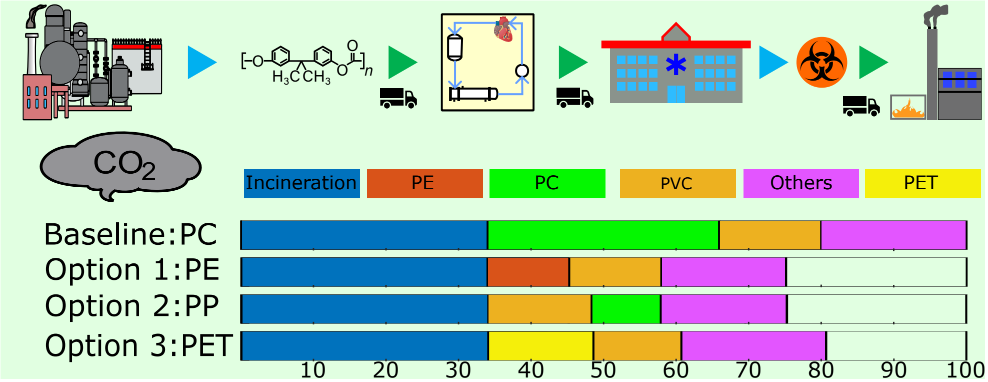

Highlights

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- Incineration emits the greatest carbon dioxide throughout the device's life cycle.
- Substituting polyvinyl chloride with other polymers decrease health effects of the device.
- Polycarbonate has the highest contribution in each impact category.
- Monte Carlo simulation is performed to characterize uncertainty.

Comparative Life Cycle Assessment of Single-Use Cardiopulmonary Bypass Devices

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Abstract

The purpose of this study is to evaluate the impacts of the common cardiopulmonary bypass device over its life cycle. This represents the first such assessment of a complex medical device, to the best of the authors' knowledge. This study was motivated by practitioners' concerns over cardiopulmonary bypass devices constructed mainly of single-use plastics, such as polyvinyl chloride and polycarbonate. The open-source software OpenLCA was used to perform each life cycle assessment with respect to ten common impact categories: global warming, eutrophication, acidification, smog, human health cancer, human health non-cancer, water intake, human health air pollutants, ecotoxicity, and natural resource depletion. The environmental impact was evaluated using the Building for Environmental and Economic Sustainability impact assessment method. To quantify the uncertainty in the results, Monte Carlo simulation was used using 5000 runs. A comparative assessment was conducted to determine the potential trade-offs in each impact category of using alternative construction materials. Incineration as a common disposal option could contribute up to 33 % of total CO_2 equivalent

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emissions over the life cycle of the device. Another 33% of total CO_2 equivalent emissions are attributed to polycarbonate used in the construction of devices. Polycarbonate was also implicated as the top contributor to the other impact categories considered, except for human health cancer, which is almost entirely affected by the use of polyvinyl chloride in the device, primarily in the tubes. The accuracy of these results is corroborated by the uncertainty analysis. Lastly, the results show that replacing polycarbonate with polyethylene terephthalate, polypropylene, or polyethylene would be no worse than polycarbonate and provide a significant decrease in almost every impact category. Cardiopulmonary bypass devices are constructed primarily of single-use plastics that have relatively significant impacts in the 10 common categories considered. Alternative disposal methods and replacement of polycarbonate with alternative plastics could dramatically reduce the effects in most impact categories.

Keywords: medical waste, single-use plastics, reusable medical devices, perfusion circuits, impact analysis, uncertainty analysis

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1. Introduction

In the United states (US) and many other industrialized countries, economic expansion and technological advancement are driven primarily by the healthcare industry (Nunn et al., 2020). In 2017, global healthcare spending was reported to be US$7.8 trillion, accounting for almost 10% of the global gross domestic product (GDP). This is due to the profits associated with the healthcare sector (Nunn et al., 2020). For example, the healthcare sector in the US is a significant generator of economic growth and innovation, accounting for US$2.8 trillion in 2012 and 17% of the country's GDP. Sixty years ago, the healthcare sector represented only 5% of the US economy, while in 2018, it represented 17.7%; a three-fold increase (Thiel et al., 2015).

Although the benefits attributed to the medical sector locally and globally are numerous, environmental costs are often ignored (Thiel et al., 2015). The consumption of resources in this major industry has reached unsustainable levels in several categories, including energy use, material use, and emissions. For example, healthcare accounts for between 3% and 4% of national greenhouse gas (GHG) emissions in the United Kingdom (UK) (Eckelman et al., 2018). In contrast, a 2013 study in the US indicated that the healthcare sector contributed between 9% and 10% of national GHG emissions (Eckelman and Sherman, 2018). Another major negative contribution of hospitals is their plastic waste. Therefore, to deal with this, environmental initiatives in hospitals tend to focus on waste reduction. However, given the size and the interconnected nature of the healthcare industry in the US, the implications of the supply chain, energy use, and emissions are crucial (Peng et al., 2020; Kenny and Priyadarshini, 2021).

The use of plastics in medical devices has increased dramatically in the past half century, becoming a common material in this industry (Unger et al., 2017). Every year, the US healthcare system creates more than 5 billion pounds of plastic waste (Wisniewski et al., 2020). The problem of medical waste can be further exacerbated by the rise of chronic diseases, as developed and developing countries around the world implement better infectious disease policies to deal with pandemics, such as Ebola and COVID-19 (Peng et al., 2020). Infectious diseases are also increasing around the world, which means that more waste is generated (Voudrias, 2018).

One of the main contributors to medical waste comes from the operating room, which is the second largest producer of hospital trash. The primary interest in this study is a medical device used in operating rooms for perfusion, called a cardiopulmonary bypass (CPB) device, which is illustrated in Figure 1. This is a type of extracorporeal circulation device in which the patient's blood is diverted from the heart and lungs and redirected outside the body for oxygenation through a series of components. Until now, there has been no regulation for the reuse or recycling of perfusion device waste (DiNardo and Zvara, 2021) and a typical CPB device generates approximately 15 pounds of plastic (Sarkar and Prabhu, 2017) that goes to incinerators after use (Wisniewski et al., 2020). Pumps, cannulae, tubing, reservoir, oxygenator, heat exchanger, and arterial line filter are the main components of the CPB circuit (Molyneux and Klein, 2015; DiNardo and Zvara, 2021). These are made mainly of polyvinyl chloride (PVC)—primarily for tubing—and polycarbonate—primarily for component casings (Qi et al., 2018; Wisniewski et al., 2020), and therefore represent the majority of the waste generated from the use of CPB devices.

One possible remedy to reduce waste is to use reusable components in perfusion devices. However, the cleaning process of reusable equipment requires energy, water, chemicals, and labor, while disposables may need additional materials in terms of production, transportation, and disposal (Sanchez et al., 2020). Also, material composition, packaging, reuse, and pricing of reusable and disposable devices can be different, as noted in a study by Eckelman

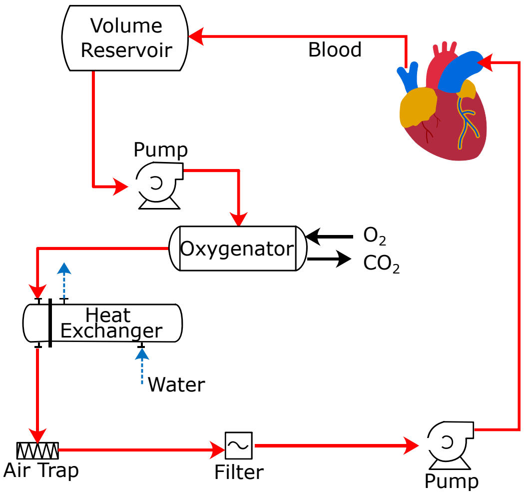

Figure 1: A process flow diagram of a CPB device is illustrated. The system is comprised of a blood volume reservoir, an oxygenator that separates CO_2 from the blood and adds oxygen, a heat exchanger that maintains the blood temperature, an air trap that captures noncondensible gas bubbles, a final filter, and two circulation pumps.

et al. (2012).

The use of a reusable device is generally considered a more environmentally friendly option than using a single-use device (Lee et al., 2021; Sanchez et al., 2020; Eckelman et al., 2012; Sherman et al., 2018; Leiden et al., 2020). However, not all reusable devices have a lower environmental impact than disposable ones. Leiden et al. (2020) performed a study on the environmental impact of disposable and reusable sets of lumbar fusion surgical equipment. The disposable system was found to have a much lower environmental impact in all impact categories investigated (Leiden et al., 2020). In another study by Allison et al. (2020), it was indicated that reusable masks could have a lower environmental impact than disposable varieties depending on the type and construction material used (Allison et al., 2020).

In recent decades, environmental issues such as global warming, pollution, and waste generation and management have become increasingly important to the international community with relatively recent interest in the healthcare sector. Life cycle management is used by corporations today as a means to improve their environmental practices and habits. Therefore, to evaluate the environmental impact of reusable and disposable medical devices, life cycle assessment (LCA) can be used. LCA is a general method of evaluating the environmental impacts of products at every stage of their life cycle, which allows for comparisons with other processes (Sherman et al., 2018; Alhazmi et al., 2021; Iswara et al., 2020) and alternative product and process design strategies. LCA takes into account resource inputs and emissions during the entire life cycle of a product (i.e., "cradle-to-grave"). This can consist of the extraction of raw material, production, transportation and disposal, and waste treatment (Lee et al., 2021; Sherman et al., 2018). LCA could eventually help to adopt activities with fewer environmental impacts and reject activities with greater environmental impacts (Dastjerdi et al., 2021).

In a study by Unger and Landis (2014), a comparative LCA was conducted to examine the environmental implications of disposable and reusable dental burs. The results of this study indicated that sterilization is a deciding factor to make the reusable device environmentally favorable. For example, in eight of the nine environmental impact categories, reusable dental burs had a greater negative environmental impact than disposable burs when autoclave and ultrasonic sterilization devices were loaded to approximately one-third capacity, while reusable burs had a 40% lower environmental impact than disposable when autoclave and ultrasonic sterilization devices were loaded to their maximum capacity (Unger and Landis, 2014). This represents the importance of conducting an LCA of disposable options to choose the best sterilization process when it comes to reusable devices.

Due to growing concerns in recent years about the negative impacts of single-use plastic medical devices, this study aims to conduct an LCA for single-use CPB devices; considered to be complicated medical devices, as they are comprised of many smaller parts. To the best of our knowledge, there are currently no published LCAs for complicated medical devices, such as a CPB. This work can help researchers and practitioners better understand the negative environmental impacts of the production and use of CPB circuits. Additionally, the model provided in this study can be used to design more sustainable reusable perfusion devices by substituting more environmentally friendly materials in production and as well as identify a better disposable method.

2. Methods

The presented LCA for disposable CPBs was performed according to international standard LCA techniques (ISO 14040: 2006) (International Organization for Standardization, 2006). As illustrated in Figure 2, cradle-to-grave was the scope of our analysis, which included material and energy resource extraction, manufacturing, packaging, and transportation from the manufacturing site to the distribution center and hospital, reprocessing, and final disposal. Figure 2(a) shows the scope of this study for the disposable device, while Figure 2(b) shows the possible scope that a reusable device may have. It should be noted that in this study, the analysis is performed only on disposable devices since there are no readily available data on reusable CPB devices as a result of the absence of current standards for the reuse or recycling of perfusion waste (Wisniewski et al., 2020). Pictures of the main individual parts and the assembled CPB device considered in this study are shown in Figure 3. For greater accuracy, the LCA was conducted with respect to 100 CPB devices for the UConn Health Hospital, reflecting a realistic scenario that many devices are purchased and ordered at once versus one-by-one.

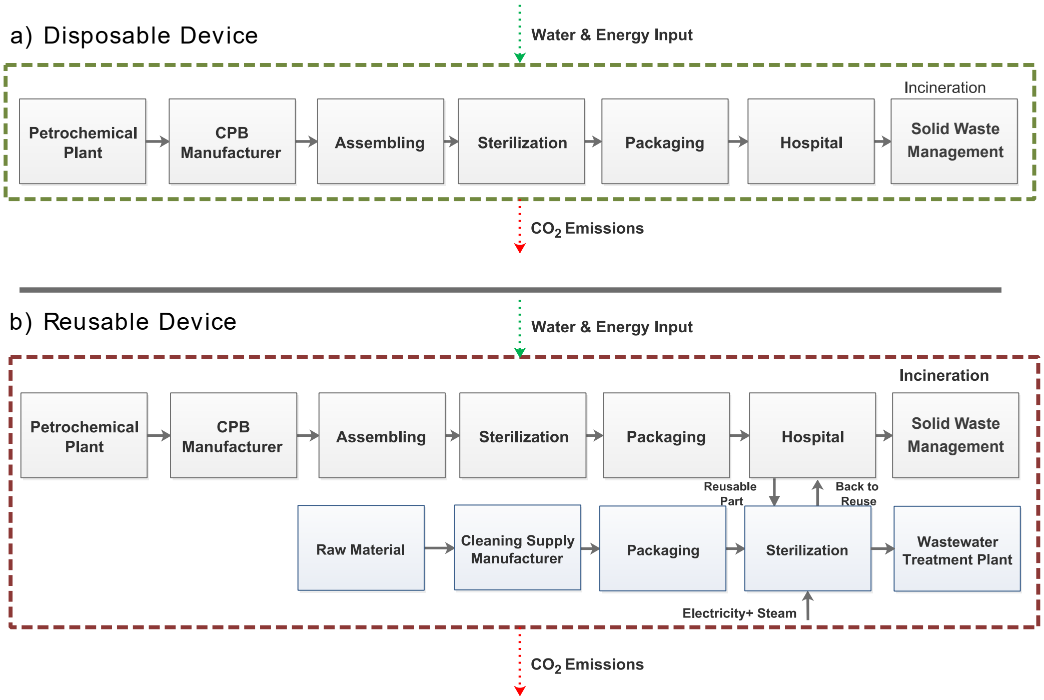

Figure 2: Block-flow diagrams are illustrated along with their corresponding system boundaries for cradle-to-grave perspectives of a) disposable devices and b) reusable devices.

The open-source software OpenLCA (Ciroth, 2007) version 1.10.3 was used to perform the analysis with the National Renewable Energy Labora-

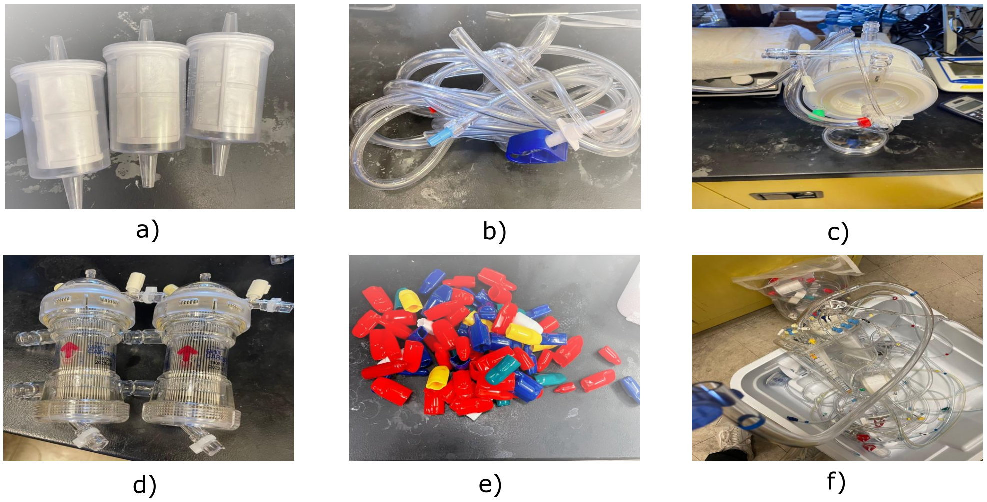

Figure 3: Photographs of the individual parts of the cardiopulmonary bypass device are provided: a) filters b) tubes c) oxygenator d) heat exchangers e) caps and nozzles, and f) the fully assembled device.

tory/USLCI (NREL) database. The environmental impact was evaluated using the Building for Environmental and Economic Sustainability (BEES) impact assessment method, which takes into account both environmental, economic, and social impacts over the entire life of a building product (Eckelman et al., 2012; Kneifel et al., 2018). Global warming, acid rain, resource depletion, indoor air quality, solid waste, eutrophication (unintentional addition of mineral nutrients to soil and water), ecological toxicology, human toxicity, ozone depletion, and smog are some of the environmental impact categories that can be measured throughout the life of a product when BEES is used (Kneifel et al., 2018). The modeling files are available at our GitHub repository `https://github.com/PSORLab/LCA/tree/main/CPBdevice`.

2.1. Modeling Parameters and Assumptions

All required modeling parameters were determined with respect to the UConn Health location in Hartford, Connecticut, USA. The material compositions of all the components studied were specified by cross-referencing the manufacturer's specifications with the component deconstruction and density testing performed for this study. The weights of the device components were determined using an A&D (Ann Arbor, MI, USA) microgram weighing scale model HR-202i with an error of ±1 mg.

Table 1: Each component of the CPB device considered is tabulated along with its weight and material classification. Each weight is accurate to ±1 mg.

Product	Weight(g)	Material	Symbol
Joints	78.080	Polyethylene	W_1
Centrifugal pump	120.770	Polycarbonate	W_2
Heat Exch. (shell)	115.985	Polycarbonate	W_3
Heat Exch. (tubes)	347.955	Stainless steel	W_4
Filters	220.780	Polyester	W_5
Tubes	1608.430	PVC	W_6
Flow Pinchers	34.920	Polyethylene	W_7
Oxygenator	556.560	Polycarbonate	W_8
Joint Tubing	4.100	Polyethylene	W_9
Tube Organizer	31.750	Polyethylene	W_{10}
Valve Control Tubing	40.950	Polyethylene	W_{11}
Plastic Package	41.300	Polyethylene	W_{12}
Connector	13.240	Polyethylene	W_{13}
Nozzle and Caps	290.200	Polypropylene	W_{14}

The CPB device consists primarily of PVC and polycarbonate components, similar to other medical devices. The device's heat exchanger is a shell-and-tube design with a polycarbonate shell and stainless steel tubes. Other designs may use PVC tubes; however, these are not considered in this study. The filters are made of polyester fiber, considered here to be the most ubiquitous polyethylene terephthalate (PET) (Ratner, 2012). The complete list of the CPB components, their weights, and their material type is shown in Table 1. Previous studies on CPBs confirm the composition and materials that were identified for this study (Bartuli and Borkovec, 2020; Wisniewski et al., 2020; Molyneux and Klein, 2015). However, more detailed material information from suppliers may allow for a more accurate analysis. Minor components, such as inks and packaging labels, were also excluded from the analysis because they are expected to have negligible effects (Eckelman et al., 2012). To have an accurate assessment of the global warming effect and CO_2 emissions during incineration, it is assumed that 2.9 kg CO_2 is emitted per kg of plastic burned (Vanderreydt et al., 2021).

Accurate accounting for transportation in this LCA is important, as the manufacturing of CPB devices involves several steps performed at distant facilities across state lines. The transportation steps considered in this study are represented in Figure 2(a) by the arrows that connect the adjacent blocks. There may be a high degree of uncertainty in the LCA due to transportation considerations, as exact modes and routes are unknown. Additional assumptions are provided in the following list, which is required to establish well-defined transportation costs for the cradle-to-grave perspective.

1. For the purposes of establishing a reasonable baseline, it was assumed that all transportation was by truck for every step from the petrochemical plant to the incinerator.
2. When several probable routes exist between a source and a destination, all corresponding distances are averaged.

The specific transportation details for this LCA are described here for the cradle-to-grave perspective. The CPB devices considered in this study were manufactured by Terumo Cardiovascular (Ann Arbor, MI, USA), and it is assumed that they receive their raw material from one of their closest petrochemical plants: Imperial Oil (Sarnia City, Canada) and LyondellBasell (Morris, IL, USA). The manufactured components are then sent from Ann Arbor, MI, to Ashland, MA, where the assembly of different components of the device takes place. The device is then shipped from Ashland to New York City, where the equipment is sterilized. The device is then shipped to Tennessee, where it is packaged and ready to be sent to hospitals. Finally, the device is shipped to UConn Health (Hartford, CT) for patient end-use and to the Hartford municipal solid waste facility thereafter to be incinerated. A summary of all distances used is shown in Table 2.

Table 2: The average distances are tabulated for each transportation step considered in the cradle-to-grave LCA for the disposable cardiopulmonary bypass device.

Steps	Distance (km)	Symbol
Petrochemical plant to manufacturer	301.0	D_1
Manufacturer to assembly	1233	D_2
Assembly to sterilization	317.0	D_3
Sterilization to packaging center	1478	D_4
Packaging center to UConn Health	1670	D_5
UConn Health to municipal solid waste plant	17.70	D_6

2.2. Uncertainty Analysis

Uncertainty here refers to the fact that measured values typically vary from actual values in a probabilistic way without exact accuracy (Ciroth et al., 2004). One way to account for uncertainty and its impacts on an LCA is to use Monte Carlo simulations (i.e., a random sampling and statistical modeling procedure (Raychaudhuri, 2008)) to help quantify the error/deviation associated with calculated results. Such an analysis is critical to assessing the accuracy of the LCA and providing confidence levels for the results.

An uncertainty analysis was conducted for this study using Monte Carlo simulations within the OpenLCA software. Uncertainty in the modeling parameters, such as transport distances and material weights, was accounted for using probability distributions. Uncertainty data, such as mean, standard deviation, min/max values, and others, were first added to the OpenLCA model for all model input flows. Table 3 contains the mean μ and the standard deviation σ values used for all the input parameters in this study. Then, the type of distribution was selected, such as normal, logarithmic, triangle, or uniform. Finally, the number of samples for Monte Carlo simulation must be set. In a typical Monte Carlo study, the number of tests/samples chosen is may be arbitrary or domain specific, falling anywhere from 10^3 to 10^4 for LCAs (Giuliana et al., 2022). The results from the Monte Carlo simulations are then probability distributions for every calculated flow type and each impact category, with which the accuracy of the LCA results can be assessed.

The following assumptions and conditions were set for this uncertainty analysis:

1. Uncertainties in the measured material weights can be calculated from the weight scale error of ± 1 mg. This value is used to calculate the standard deviation for each weight used in the analysis for sampling a normal distribution for Monte Carlo simulation as $3\sigma = 1$ mg.
2. All input parameter values are normally distributed except for D_1, which is considered to be uniformly distributed.
3. Monte Carlo simulations are performed with 5000 runs/samples.
4. The uncertainty for each category is calculated as the standard deviation divided by the corresponding mean.
5. The uncertainty is considered *significant* if it is ≥ 0.3 and the corresponding LCA results may be considered unreliable (Giuliana et al., 2022).

Table 3: The mean and standard deviation values for each input parameter are tabulated. These values are used in the Monte Carlo simulations for uncertainty analysis. The D_i (i.e., distance) parameters are defined in Table 2 and the W_j (i.e., weight) parameters are defined in Table 1.

Parameter	μ	σ	Parameter	μ	σ
D_1	-	-	D_2	1233	58.20
D_3	317.0	9.230	D_4	1478	53.40
D_5	1670	56.20	D_6	17.70	0.560
W_1	78.080	0.0003	W_2	120.770	0.0003
W_3	115.985	0.0003	W_4	347.955	0.0003
W_5	220.780	0.0003	W_6	1608.430	0.0003
W_7	34.920	0.0003	W_8	556.560	0.0003
W_9	4.100	0.0003	W_{10}	31.750	0.0003
W_{11}	40.950	0.0003	W_{12}	41.30	0.0003
W_{13}	13.240	0.0003	W_{14}	290.200	0.0003

3. Results and Discussion

This section is divided into three parts. First, a “Baseline LCA” is provided in which the results are presented for different impact categories for the device studied. The second part, entitled “Material Selection for Impact Reduction”, demonstrates how the CPB device may be made more environmentally friendly by substituting constituent materials. Lastly, the results are presented in “Uncertainty Analysis” for uncertainty propagation with Monte Carlo simulations for the baseline LCA.

3.1. Baseline LCA

Ten impact categories, namely global warming, acidification, eutrophication, water intake, smog, human health (HH) cancer, HH air pollutants, ecotoxicity, natural resource (NR) depletion, and HH non-cancer were assessed in this LCA. The results are plotted in Figure 4 for six environmental impact categories with respect to their greatest contributors in each category. Data for all impact categories are contained in Table 4. The results indicate that every impact category is significantly affected by all materials found in CPB devices, except HH cancer which is affected almost entirely by PVC, and NR depletion, which is mainly affected by stainless steel. Furthermore, polycarbonate is observed to be the main contributing factor for almost all life cycle impact categories, except for HH cancer and global warming, demonstrating the detrimental effects of this material. Polycarbonate is prevalent in CPB devices where it is used in the centrifugal pump, the oxygenator, and the heat exchanger shell. This result implies that polycarbonate is one of the materials for which manufacturers should find a replacement to build a more environmentally friendly CPB device.

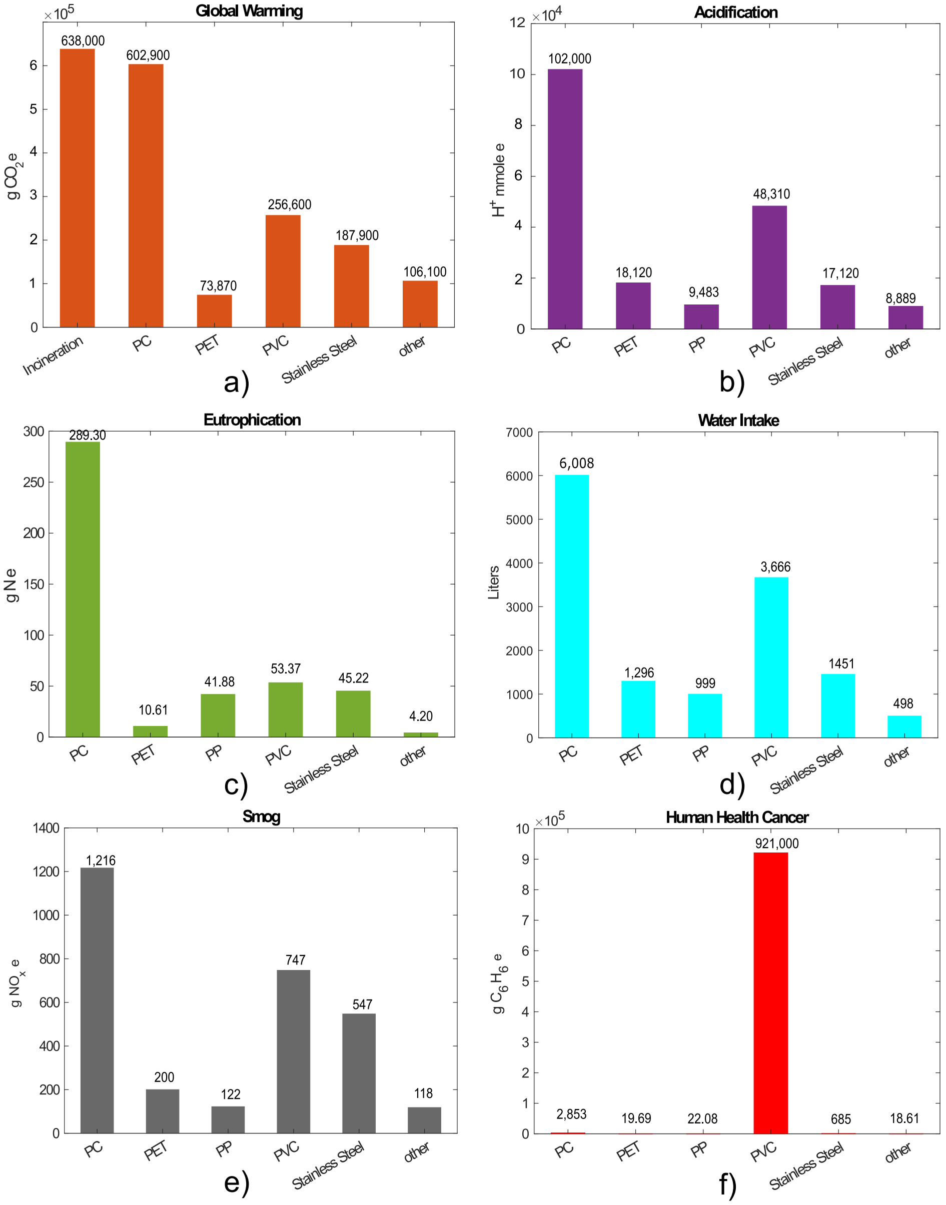

Figure 4: The LCA results are plotted for each environmental impact category in these bar charts: a) global warming impact in terms of gCO_2e, b) acidification in terms of mmole-H^+e, c) eutrophication in gNe, d) water consumption in liters, e) smog in terms of gNO_xe, and f) human health cancer in terms of gC_6H_6e. The polymers are initialized as: polycarbonate (PC), PET, PVC, and polypropylene (PP).

In addition, further focusing on the global warming impact category (Figure 4(a)), we observe that approximately 1.86×10^6 gCO_2e is released into the atmosphere when 100 CPB devices are produced for the UConn Health Hospital. Nearly 34.2% of these emissions are caused by incinerating the device. Roughly the same amount is also observed for the production of polycarbonate, as it is responsible for almost one-third of the total CO_2 equivalent emissions. PVC is the third largest contributor to global warming, albeit less than half that of polycarbonate.

To better understand the carbon footprint of the production of 100 CPB devices in relation to other single-use plastic objects, a comparison was made with the production of 1500 high-density polyethylene (HDPE) single-use shopping bags. According to Greene (2011), a cradle-to-grave LCA of the bags has a global warming impact of 4×10^5 gCO_2e. The gCO_2e amount for 100 CPB devices is almost 50 times higher than 1500 HDPE plastic bags (Greene, 2011). From this analysis, it can be concluded that it is vital to eliminate incineration to reduce the carbon footprint of CPB devices, which can be achieved by using a reusable device or using alternative disposal methods. Similarly, the elimination of polycarbonate would result in a significant reduction in the carbon footprint of these devices.

The acidification impact category results are shown in Figure 4(b). Acidification occurs when sulfates, nitrates, and phosphates (i.e., acidifying contaminants) in the atmosphere are deposited on soils, groundwater, surface waters, organisms, and ecosystems. NO_x, NH_3, and SO_2 are the major acidifiers (Bałdowska-Witos et al., 2021). Acidification potential is reported in equivalent molar hydrogen ions (mmole-H^+e) (Geyer et al., 2013). The results show that polycarbonate and PVC are the largest contributors to acidification, with polycarbonate being responsible for approximately 50% of the total mmole-H^+e, while PVC is responsible for roughly 25% of the total. Again, finding an alternative material to polycarbonate could dramatically reduce the acidification impact of the CPB devices.

Figure 4(c) depicts the eutrophication impact category, quantified in units of grams of nitrogen equivalent gNe. Eutrophication is the enrichment of nutrients in the water of aquatic ecosystems. Eutrophication in inland waters is one of the most critical phenomena affecting the ecological quality of water (Bałdowska-Witos et al., 2021). Similar to the other impact categories, polycarbonate is responsible for the largest contribution to eutrophication, accounting for approximately 65% of the total gNe.

Figure 4(d) shows the results for the water intake impact category. Based on the analysis of 100 CPB devices, the water intake associated with a single device is approximately 140 liters. The main contributors to the water intake for these devices are polycarbonate and PVC; responsible for approximately 43% and 26% of the total water intake, respectively.

The results for the smog impact category are shown in Figure 4(e). The devices contribute approximately 3000 gNO_xe over their life cycle. Similar to the other categories, the production of polycarbonate, PVC, and stainless steel are the main contributors to this environmental impact category.

Figure 4(f) shows the results of the LCA with respect to the HH cancer impact category. With regard to this impact category, almost the total impact of the disposable CPB is due to PVC production. The fact that PVC has the highest contribution is also confirmed by Eckelman et al. (2012) for disposable laryngeal mask airways. The other materials that are used in the device contribute trivially to this impact category, with the next highest contribution coming from polycarbonate, which is two orders of magnitude lower than that of PVC.

The NR depletion impact category was also assessed in this study. There are two types of effects associated with the depletion of natural resources: those caused by the removal of fossil fuels and those caused by the removal of minerals. Each of these groups is rated according to the rising costs associated with resource extraction and the results are given in megajoules (MJ) of surplus energy (Piasecka et al., 2019). Here, "surplus" refers to the future amount of energy required to extract one unit of fossil fuel (Arvidsson et al., 2021). An analysis of the depletion of natural resources (fossil fuels) for the CPB device shows that the production of stainless steel is the main source with a value of 49.17 MJ surplus (Table 4). Nearly 75% of this value comes from the consumption of crude oil, and the rest is caused by the consumption of coal.

In addition to the six major impact categories illustrated in Figure 4, HH air pollutants and ecotoxicity impacts are also investigated. Air pollutants are considered common solid and liquid particles released into the air. Electricity generation, vehicle operation, combustion, and material handling are just a few examples of the various processes that produce air pollutants. To quantify the HH air pollutants impact category, the units of disability-adjusted life years (DALYs) have been developed to measure health losses from air pollution. DALYs account for the number of years of life lost or years of disabled life, taking into account the severity of the underlying health problems (Suh et al., 2000) (measured in the micro DALYs (Wu et al., 2020)). As can be seen in Table 4 the major contributor in this category is caused by

Table 4: A summary of the LCA results are tabulated for nine impact categories assessed with OpenLCA. For each impact category, the contributions of incineration (Incin.), polycarbonate (PC), PVC, Stainless Steel (SS), polyethylene terephthalate (PET), and polypropylene (PP) are shown.

	Incin.	PC	PVC	SS	PET	PP	Total
Global Warming 10^5[gCO_2e]	6.380	6.029	2.566	1.879	0.7387	0.5647	18.65
Acidification 10^5[mmole-H^+e]	–	1.020	0.4831	0.1712	0.1812	0.09482	2.039
Smog 10^3[gNO_xe]	–	1.216	0.7470	0.5470	0.2000	-	2.946
HH Cancer 10^3[gC_6H_6e]	–	2.853	921.0	0.6850	0.01969	0.02208	925.1
HH Non-Cancer 10^6[gC_7H_7e]	–	1.454	1166	0.1231	0.002734	–	1168
Eutrophication 10^2[gNe]	–	2.893	0.5337	0.4522	0.1061	0.4188	4.446
H_2O Intake 10^3[Liter]	–	6.008	3.666	1.451	1.296	0.9990	13.92
HH Air Pollutants 10^1[microDALYs]	–	7.330	1.510	1.230	0.7100	0.3180	11.40
Ecotoxicity 10^4[g2,4-De]	–	0.8990	0.2724	0.01830	–	–	1.195
NR Depletion [MJ Surplus]	–	–	–	49.17	–	–	49.17

production of polycarbonate. Ecotoxicity is the evaluation of the impacts on the ecosystem; measured in grams of 2,4-dichlorophenoxyacetic acid (2,4-D) equivalent (Ju et al., 2019; Wu et al., 2020) (g2,4-De). 2,4-D, a phenoxyalkanoic acid, is one of the most prevalent environmental contaminants. The results for this impact category show that the major contributions are from the production of polycarbonate, PVC, and stainless steel, respectively.

Finally, the last impact category that was assessed is HH non-cancer. It is a type of impact that takes into account the negative non-cancerous effects on human health from inhaling toxic substances in the air, drinking toxic substances in water, and absorbing toxic substances through the skin (Jolliet and Fantke, 2015). The HH non-cancer impact is measured in units of gC_7H_7e (Babaizadeh et al., 2015). As shown in Table 4, the highest contributor to this category comes from PVC, with a value of 1166×10^6 gC_7H_7e. The contributions from other materials are almost negligible in comparison to PVC with values of roughly 2 gC_7H_7e. This shows that it is feasible to reduce the potential of this impact category to nearly zero if an appropriate material can be identified to replace with PVC.

There are three important takeaways from the results presented. First, since the CPB device is constructed primarily of polymers, the disposal method is extremely important for mitigating its global warming impact. Second, polycarbonate and PVC are predominantly responsible for the majority of contributions to all impact categories. Lastly, polyethylene is a relatively benign material that contributes minimally to each of the impact categories. This is especially interesting because the relative weight of polyethylene in the CPB device is greater than that of polyester/PET.

3.2. Material Selection for Impact Reduction

In the previous section, the LCA results showed that polycarbonate is one of the main contributors in each impact category. Therefore, one way to diminish the potential impact of the CPB devices is to explore alternative materials to substitute for polycarbonate. In this section, comparative analyses are conducted against the baseline LCA, considering PET, polyethylene, and polypropylene as alternative materials to replace polycarbonate. The main results are shown in Figure 5, which illustrates the effects of replacing polycarbonate by alternative polymers. The main conclusion is that eliminating polycarbonate will result in a significant decrease in all impact categories except in HH cancer, HH non-cancer, and NR depletion (which are not plotted).

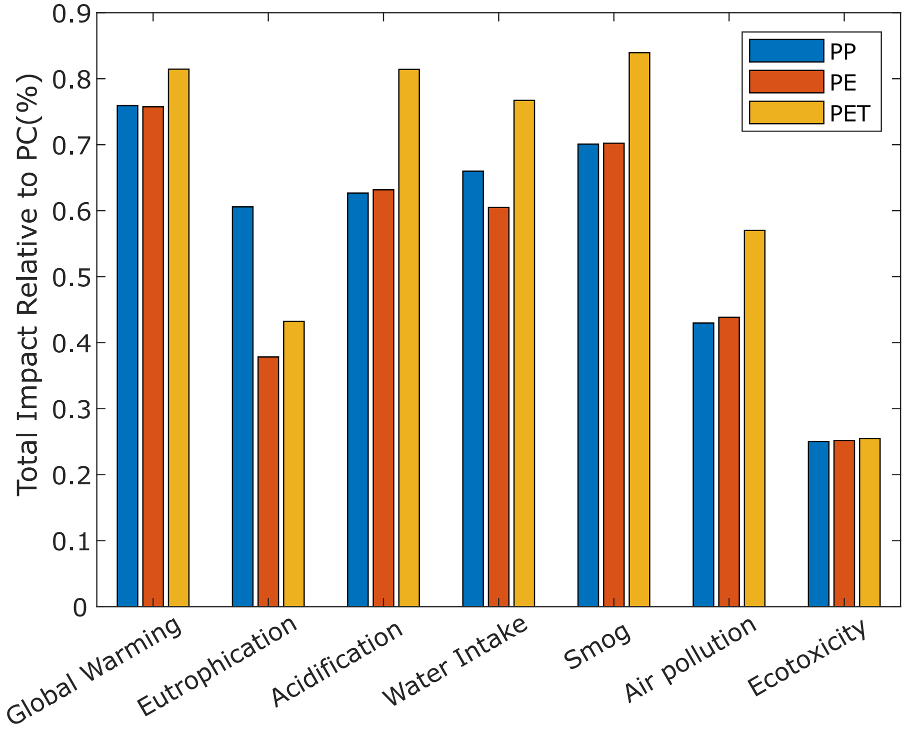

Figure 5: The LCA results for using alternative polymers (polypropylene (PP), polyethylene (PE), and PET) are plotted for eight impact categories as percentages relative to the baseline LCA using polycarbonate (PC). A value of $< 100\%$ means that the alternative polymer will result in a reduction in the value for that impact category. For example, replacing PC with any alternative polymer considered will result in a roughly 75% reduction in the ecotoxicity potential.

There are several important results that should be highlighted from the comparative assessment. First, the results for HH cancer show that this impact category does not depend on polycarbonate. Second, the replacement of polycarbonate with PET, polypropylene, or polyethylene results in an equal percentage reduction in the ecotoxicity impact category of almost 75%. Moreover, replacing polycarbonate with PET leads to a 60% reduction in the eutrophication impact of the device, which makes PET more suitable than other materials in terms of reducing this impact category potential. Furthermore, we observe that replacing polycarbonate with polyethylene leads to a greater decrease than polypropylene in almost all categories. This indicates that polyethylene could be a very suitable option for replacing polycarbonate, over other alternatives, from the perspective of purely reducing all impact categories.

3.3. Uncertainty Analysis

The findings of the LCA should be as accurate as possible, however; limitations in understanding, faulty measurements, and low-quality data present errors. To determine the impact categories most sensitive to uncertainty in the input data, Monte Carlo simulation was used. The key outcomes of the uncertainty analysis are displayed in Table 5, including the mean μ, standard deviation σ, and uncertainty values. The results indicate that for all impact categories, the uncertainty is < 0.3, indicating that the results of this study are accurate.

Another notable finding is that global warming has the highest uncertainty compared to other impact categories. This may be due to additional sources of uncertainty that do not affect the other categories. The primary sources of uncertainty stem from measurement error in the weights of the components, the travel distances (since it was shown that there are multiple possible routes), and in the case of global warming, the quantity of CO_2e emitted in incinerating one kilogram of plastic.

Table 5: The results for the uncertainty analysis are reported. The mean and the standard deviation of the Monte Carlo simulations are reported for each impact category.

Impact category	μ	σ	uncertainty
Global warming	1.865×10^{6}	6.624×10^{2}	3.551×10^{-4}
Eutrophication	4.446×10^{2}	2.165×10^{-4}	4.869×10^{-7}
Smog	2.947×10^{3}	1.088×10^{-3}	3.691×10^{-7}
HH criteria air pollutants	1.142×10^{2}	5.492×10^{-5}	4.809×10^{-7}
HH non-cancer	1.168×10^{9}	2.322×10^{2}	1.988×10^{-7}
HH cancer	9.251×10^{5}	1.830×10^{-1}	1.978×10^{-7}
Acidification	2.040×10^{5}	8.020×10^{-2}	4.019×10^{-7}
Ecotoxicity	1.195×10^{4}	6.411×10^{-3}	5.364×10^{-7}
NR depletion	4.917×10^{1}	4.655×10^{-5}	9.465×10^{-7}
Water intake	1.392×10^{5}	1.534×10^{-2}	1.102×10^{-7}

4. Conclusion

This work presented a life cycle assessment (LCA) of a cardiopulmonary bypass device (CPB), which is the first study on a such complex medical device, to the best of the authors' knowledge. This study was conducted to establish a baseline of environmental impact for assessing future alternative designs and/or processes in healthcare settings to address the growing problem of medical waste. The results of the LCA enabled the identification of the main components of the CPB device that are responsible for the greatest negative environmental impacts. Through deconstruction of the device and component density tests, it was found that the device consists mainly of PVC and polycarbonate. The LCA showed that disposal by incineration of these materials can contribute up to one third of the CO_2 equivalent emissions over the life cycle of the device and that alternative disposal methods should be considered. It was also found that using PVC as the material for the device's tubes is detrimental to human health, as was shown in the human health cancer impact category.

A comparative assessment was also conducted to explore the impact category trade-offs of using alternative polymeric materials in the CPB device. Alternatives of polycarbonate were considered as polypropylene, polyethylene terephthalate, and polyethylene. Up to an 80% decrease in some impact categories was observed through the replacement of polycarbonate. Furthermore, polyethylene exhibited the largest decrease in eutrophication impact than the other alternative materials considered.

Despite several novel contributions of this study, there are some limitations worth noting. Unlike some LCA studies that focus on comparative assessment and sustainability of single-use materials and devices, this study does not consider the case of a reusable device. This is not only because a reusable device does not currently exist but, more importantly, a hypothetical scenario would likely be inaccurate, as there are many outstanding issues surrounding reusable medical devices that are beyond the expertise of the authors. These issues relate to material selection, device construction, and novel sterilization procedures, among others, to eliminate disease transmission and infection risks.

Nevertheless, the results of this study can help manufacturers better assess the sustainability of their CPB devices. These results may serve as a basis for designing more environmentally friendly components, such as those that can be reused (if possible, considering infection transmission as a factor), or those that simply have reduced negative impacts on the environment by utilizing alternative materials. The results also illustrate the importance of the medical waste disposal method for single-use devices and the potential benefit of choosing alternative disposal methods and/or the introduction of reusable device designs.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Abbreviations

BEES	Building for Environmental and Economic Sustainability
CPB	Cardiopulmonary Bypass
DALYs	Disability-Adjusted Life Years
GHG	Greenhouse Gas
GDP	Gross Domestic Product
HDPE	High-Density Polyethylene
HH	Human Health
LCA	Life Cycle Assessment
MJ	Megajoules
NREL	National Renewable Energy Laboratory
NR	Natural Resource
PC	Polycarbonate
PE	Polyethylene
PET	Polyethylene Terephthalate
PP	Polypropylene
PVC	Polyvinyl Chloride
SS	Stainless Steel
US	United States

UK	United Kingdom

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