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Iqbal Akhtar Khan *

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Review Article

From Baby Fae to Lawrence Faucette: A Fascinating Tale of Cardiac Xenotransplantation

Iqbal Akhtar Khan

MBBS DTM FACTM PhD, Independent Scholar, Lahore 54792, Pakistan.

Corresponding Author: Iqbal Akhtar Khan, MBBS DTM FACTM PhD, Independent Scholar, Lahore 54792, Pakistan.

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Abstract

The first cardiac xenotransplant was attempted by Hardy on January 23,1964 at the University of Mississippi Medical Center, using a chimpanzee donor, on a 68-year-old male patient suffering from heart failure. But the heart was too small to support the patient's circulation, and graft loss occurred in 2 hours, because of antibody-mediated rejection. On October 26, 1984, at Loma Linda University Medical Center California, Bailey transplanted a baboon heart into Baby Fae. She took an additional 20 days in her life. The medical miracle turned out to be one of the most controversial procedures in the history of medicine, triggering controversy from many within the medical field and animal rights organizations across the country. On January 7, 2022, in a first-of-its-kind surgery, David Bennett a 57-year-old patient, with terminal heart disease, received a successful transplant of a genetically modified pig heart at the University of Maryland Medical Center by Mohiuddin and Griffith. The patient lived 60 days postoperatively. The world's second patient Lawrence Faucette 58 years underwent xenotransplantation with a genetically modified pig heart, on September 20, 2023. The procedure was carried out by the same enthusiastic team, in the same Center.To begin with, he had made significant progress after his surgery. However, with passage of time his heart began to show initial signs of rejection and ultimately, he succumbed on October 30, 2023. This is not the end of the story. The unremitting journey, backed by creativity, courage and determination continues because "*the surgeons, by nature, tend to be optimists*".

Keywords: cardiac xenotransplantation; baboons; Pigs; baby fae

Introduction

"We have a long way to go before xenotransplantation is available to the masses, but we will push forward into the phase of making this breakthrough treatment a reality".

Jayme Locke, UAB [1]

Xenotransplantation (Cross-species transplantation) is defined by the US Food and Drug Administration (FDA) as: "*any procedure that involves the transplantation, implantation or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source, or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs*" [2]. Of note, the xenotransplantation neither aims nor can replace allotransplantation which typically refers to inter-human transplants of solid organs: kidneys, lungs, pancreas, liver and heart through a surgical procedure in which a failing or damaged organ in the human body is replaced with a healthy one [3]. The concept of cross-species transplantation has a long and venerable history. Many legends exist in folklore in which one body part is replaced with that of an animal. For example, Anubis, one of the most important gods in Ancient Egypt, was depicted as a jackal-headed god. He was said to have invented the mummification process. Hindu deity Ganesh's human head was replaced with that of an elephant. Greek mythology had multiple chimeric figures, including a minotaur born with a bull's head, centaurs with human torsos and heads but the lower body resembled that of a horse, and the sphinx has the head of a woman, the haunches of a lion, and the wings of a bird [4]. The earlier attempts of xenotransplantation, dates back to June 12,1920 when French Surgeon of Russian origin Serge Voronoff started for Rejuvenation Surgery. He got fame as "monkey gland man", "The doctor using Monkey Testicles to Make Us Immortal" and famous poet Cummings's Song "The doctor who inserts monkey glands in millionaires" [5].

The present study is aimed at appraising the readers of academic history of xenotransplantation. Guidelines of Hamilton College for "Writing a Good History Paper" were followed. Library immersion, analysis of archives and web search were the mainstay of the sources. The written primary sources of information were letters, diaries, memories, speeches, church records and newspaper articles. The secondary sources included scholarly write-ups of "disinterested observers" who were, by any means, connected to the series of events; and also, the unbiased historians [6].

Early Cardiac Xenotransplantation Attempts

"The development of xenotransplantation is, in part, driven by the fact that the demand for human organs for clinical transplantation far exceeds the supply [2–FDA] The first cardiac xenotransplant was attempted by Prof. James D Hardy (1918-2003), on January 23,1964, at the University of Mississippi Medical Center, using a chimpanzee donor, on a 68-year-old male patient suffering from heart failure. But the heart was too small to support the patient's circulation, and graft loss occurred in 2 hours because of antibody-mediated rejection [7]. In 1977, Prof. Christiaan Barnard (1922-2001) conducted a xenotransplant using chimpanzee heart. It was heterotopic heart transplantation (HHT) which is a surgical procedure that allows the graft to be connected to the native heart in a parallel fashion. The main advantage of HHT is to assist the patient's native heart and to maintain circulation in the cases of severe acute rejection [8]. Its survival was 4 days [9]. On October 26, 1984, at Loma Linda University Medical Center California, Prof. Leonard L Bailey transplanted a baboon heart into Stephanie Fae Beauclair (Baby Fae). The case is being discussed in detail, in the following paragraphs.

Baby Fae: The First Successful Infant Recipient of Cardiac Xenotransplant

"Infants with heart disease yet to be born will someday soon have the opportunity to live, thanks to the courage of this infant and her parents."

Prof. Leonard L Bailey— at News Conference on October27, 1984 [10]

Baby Fae (nicknamed to protect the anonymity of her parents) was born pre-maturely, at a Community Hospital in the high-desert city of Barstow (California), on October 14, 1984.Within a few hours, she was rushed to Loma Linda University Medical Center where she was diagnosed with 100% lethal hypoplastic left heart syndrome by Dr. Dougals Deming, the perinatologist/neonatologist. The gravity of the situation was notified to the mother whose reaction was very severe, though not unnatural. She cried "*You mean you can put a man on the moon; but there is nothing you can do to help her*". Unfortunately, Dr. Deming had nothing say except "No, very sorry". The young mother was given a choice:

(i) Let her baby die in the Loma Linda Medical Center

(ii) let her die at the community hospital in Barstow

(iii) let her die at home [11]

She left the Center with heavy heart and checked into a motel in Barstow.

After a few days, she called the University Medical Center to report that the infant was becoming jaundiced. At that time Dr. Leonard Bailey, had returned from Hospital for Sick Children in Toronto, Canada, with seven years involvement in studies related to the treatment of infants with that malady. With no possibility to immediately get a human donor for allotransplantation, Dr. Bailey decided to utilize his experimental work in Toronto where he had performed over 200 procedures on animals (including baboons) [12]. He decided to speak directly with the parents, explain to them the actual situation and various available options. During the discussion for more than seven hours, he explained to them that from the background knowledge, the baboons were an extremely important asset in xenotransplantation research and for practical reasons, younger, smaller female baboons were the most valuable [13]. At the end of the day, the parents agreed on experimental baboon-heart transplant for their daughter and gave Dr. Bailey the written authorization to perform the testing on their daughter to determine which of the twelve baboons that the medical center had in the facility would be the best match. Dr. Sandra Nehlsen-Cannarella, the consultant immunologist, reported that Baby Fae showed the least reaction immunologically to a seven- month-old female baboon named "Goobers" [14]. The surgery date was set for October 26, 1984. After inserting the new heart and connecting it, the chest cavity was closed, and her body temperature was slowly raised. The donor heartbeat spontaneously as Baby Fae's body rewarmed from sixty-eight to ninety-eight degrees. "*We were blessed*," Bailey said. "*It just turned out beautifully. Her response to the surgery was just perfect*." [wondering world 1985]. After successful completion of the procedure, things went smooth. But, despite having the best medical care available, Baby Fae died at 9:00 p.m. on November 15, after holding on for 20 days. However, she became the longest-living recipient of a cross-species heart.

According to Bailey:

"Autopsy findings showed only traces of cell-mediated rejection. Graft failure appears to have resulted from a progressive, potentially avoidable humoral response, unmodified by immunosuppression, perhaps as a result of crossing the ABO blood barrier" [15]. The medical miracle turned out to be one of the most controversial procedures in the history of medicine, triggering controversy from many within the medical field and animal rights organizations across the country. While Bailey and the medical staff focused all their energy on Baby Fae, around 275 journalists, including TV news crews, converged on Loma Linda University expressing their outrage on the transplant procedure viewing the loss of baboon's life as not only unethical, but inhumane. They were carrying signs that read: "Animal Research is Scientific Fraud", "Animal Experiments Never Cured Anything", "Animal Researchers Are Quacks", and the like. Threatening and hateful messages were sent to Dr. Bailey. Due to genuine security risks he had to seek police protection. Lucy Shelton of People for the Ethical Treatment of Animals (PETA) thundered "This is medical sensationalism at the expense of Baby Fae, her family and the baboon". Prof. Tom Regan, American philosopher specialized in Animal Rights Theory, wrote "the baboon was more than a resource for Baby Fae's body, "Those people who seized [Goobers'] heart, even if they were motivated by their concern for Baby Fae, grievously violated Goobers' right to be treated with respect." Michael Giannelli, Science Advisor for the Fund for Animals remarked: "I don't believe what was done was in the best interest of Baby Fae,' it may have been in the best interest of Loma Linda doctors. In a press interview on November 5, 1984, Dr. Jack Provonsha, the Director of Loma Linda University's Center for Christian Bioethics, was asked about the possibility that the baboon is "sacrificed for a chancy operation". His comprehensive answer was very logical:

"We do not know what the possibilities are for success or even what constitutes full success. A crystal ball is not an item in our medical equipment. Rejection, of course, means trouble. All we can say is that the baby would have a chance with the surgery." "On an ethical-value scale, we will always place human beings ahead of sub-humans, especially in a situation where people can be genuinely served by animals. That is the story of mankind from the very beginning. Animals, for example, have always been used for food and clothing. I would not want to sacrifice even a baboon meaninglessly, however. But to do so to save the life of a baby seems to me to be perfectly in order [14]. Although the medical community recognized the procedure a medical breakthrough, it was split regarding the possibility of success of the transplant.

John Sarkis Najarian (*1927 –2020*), University of Minnesota transplant surgeon, remarked "there has never been a successful cross species transplantation. To try it now is merely to prolong the dying process. I think Baby Fae is going to reject her heart. An editorial and medical review from JAMA concluded that the transplantation was doomed to fail because of basic incompatibility between humans and baboons and the hopes for a successful transplant by Bailey and his team were "wishful thinking." However, there were some supportive voices from certain corners.

"Dr. Bailey, his colleagues, and his hospital deserve praise, not condemnation, for trying. Their experiment, born of desperation, may yet be tomorrow's breakthrough for untold numbers of babies" [14]. Joanne Jacobs, a columnist in the San Jose Mercury-News, said: "I am glad Baby Fae got a chance too: trying to save her, even at desperate odds with experimental techniques, was the humane thing to do. I wouldn't want to live in a society that let its children die without a fight" [14]. There was another voice of encouragement from Stuart W. Jamieson, transplant surgeon of Stanford University "I was "rather disappointed to hear that people in the scientific community have leveled charges that they (the Loma Linda team) were unprepared. I don't believe that any of that is correct, it was a legitimate and timely thing to do" [14]. From certain other corners, there were positive comments.

"Dr. Bailey, his colleagues, and his hospital deserve praise, not condemnation, for trying. Their experiment, born of desperation, may yet be tomorrow's breakthrough for untold numbers of babies".

The Death of Baby Fae was Not Meaningless:

"The great medical team at highly respected Loma Linda University Medical Center has demonstrated medical science at its best. And even if Baby Fae does not survive, she and her doctors will have advanced medical knowledge for the ultimate benefit of mankind.

The San Diego Union, Editorial November 3, 1984 [14].

At a press conference on November 16, 1985, Dr. Bailey pledged to honor the request of her mother that this experience not be wasted and that he would attempt the operation again "by and by". The death of Baby Fae was not meaningless. Bailey performed the first successful transplant of a human heart into a human infant, at the time known as Baby Moses but later identified as Eddie Anguiano. The heart, donated by the family of an infant in the San Francisco Bay area, still pumps in his chest. On December 9, 2014, he, with his mother, had an informal reunion with Dr. Bailey. This was a very sentimental moment when the patient and his mother paid tribute to the surgeon who dared to care him 29 years ago [16]. Of note, Baby Fae was the first human to receive a transplanted baboon heart from Bailey, and the last. Bailey never did a second transplant of a non-human heart on a human [10]. During his professional career, Bailey transplanted human hearts into 376 infants, earning a global as a pioneer in infant heart transplantations and as a leading authority on congenital heart surgery. [10]

How did the Pig Organs Make their Way into Humans?

"When you think about trying to ramp up xenotransplant in relatively short order and keep pace with the demand, the pig offers a great opportunity for that," Jayme Locke, UAB [1].

The motivation for using animal sources for organ or tissue transplantation is driven by supply and demand. Why to select Pigs for Cardiac Xenotransplant? The scientists generally believe that pig organs are the best source for human xenotransplantation to eliminate the organ shortage crisis. They are less likely than nonhuman primates (NHPs— a group of mammals composed of simians – monkeys (mandrills and baboons) and apes – and prosimians, such as lemurs) to transmit pathogens because they are more distantly related to humans [17]. Since pigs are omnivores like humans, their organs function in a comparable manner to human organs [18]. their tissues (such as heart valves) have been successfully transplanted into human [19]. Genetically modified, live-cell, pig skin has been successfully grafted to human burn wound. Porcine islet cells of Langerhans have been injected into patients with type 1 diabetes mellitus [20].

Their unlimited availability, good breeding potential, rapid growth, moderately close anatomical and physiological similarity to humans, early sexual maturity (5 months), short gestation periods (3.5 months) and large litters (usually 5-10 piglets but with modern or 'improved' breeds, developed and favored by commercial producers, may produce litters ranging from 14 to 20) and suitable organ size, offer advantages over other animals [21].To date, a porcine heart has been implanted into only two human recipients, which are discussed in detail in following paragraphs. At Department of Cardiothoracic Surgery, New York University Langone Health, New York, NY, Moazami et al transplanted porcine hearts into two brain-dead human recipients and monitored xenograft function, hemodynamics and systemic responses over the course of 66 hours. The first xenotransplant was performed on June 16, 2022, in a 72-year-old male recipient. The donor pig was 309 days old male. The second xenotransplant was performed on July 6, 2022, in 64-year-old female recipient. The donor pig was 329 days old male. For both hearts, the surgeons confirmed transgene expression and found no evidence of cellular or antibody-mediated rejection, as assessed using histology, flow cytometry and a cytotoxic crossmatch assay. Moreover, there was no evidence of zoonotic transmission from the donor pigs to the human recipients [22]. Since, not nearly enough donated human organs are available to meet the demand of those in dire need of, "the pig organs made their way into humans". Genetically modified pigs, after a number of manipulations which protect tissues from the recipient's immune response, would, most hopefully be a source of limitless supply of organs and tissues for those needy. The big giants in medical field are very optimistic about the future utility of pigs in xenotransplant surgery. Prof. Megan Sykes Director of the Columbia Center for Translational Immunology said: "The transplant becomes an elective procedure, and you can schedule it. You can quality control your donor. You don't have to wait for somebody to pass away for an organ to be available. This is in the future, but you can start to think about transplanting people at an earlier stage of their disease, when they haven't developed all the complications of their heart failure" [23].

David Bennett: History Making Porcine Heart Transplant Recipient:

"This was a breakthrough surgery and brings us one step closer to solving the organ shortage crisis. There are simply not enough donor human hearts available to meet the long list of potential recipients."

Prof.Bartley P. Griffith [24]

On January 7,2022, in a first-of-its-kind surgery, David Bennett a 57-year-old patient, with terminal heart disease, received a successful transplant of a genetically modified pig heart, at University of Maryland School of Medicine (UMSOM) at the University of Maryland Medical

Center by Prof. Muhammad Mansoor Mohiuddin Scientific Director Cardiac Xenotransplantation Program and Prof. Bartley P. Griffith Clinical Director [25]. After the highly experimental surgery, the patient was able to move about freely in the absence of cardiopulmonary bypass assistance. The transplanted pig heart functioned well for several weeks and displayed none of the typical signs of rejection by the patient's body, Prof. Griffith said: "We were incredibly encouraged by his progress. His heart was strong, almost too strong for his frail body, but he had a strong will to live. He told me he wanted to go home and see his dog, Lucky" [26]. Bennett's regularly visited him. He sang "America the Beautiful" while watching the Super Bowl in February with his physical therapist [Shed Light]. But his condition began deteriorating resulting in death on March 9, 2022, two months after the transplant surgery [17]. On autopsy, the xenograft was found to be edematous, having nearly doubled in weight. Histologic examination revealed scattered myocyte necrosis, interstitial edema, and red-cell extravasation, without evidence of microvascular thrombosis — findings that were not consistent with typical rejection. [24]. Prof. Mohiuddin said: "We are very encouraged by this finding, and it suggests that the genetically modified pig heart and the experimental drug we used to prevent rejection worked effectively in tandem to demonstrate that xenotransplants can potentially save future lives," [26]. Although Mr. Bennett only lived for 60 days after the surgery, the xenotransplant was considered a success. He lived longer with an animal heart than any human before. The experimental surgery demonstrated for the first time that a genetically modified animal heart can function like a human heart without immediate rejection by the body [25].

Why David Bennett was not offered Human Heart Transplant

"A human organ is considered a very precious thing. The main concern was whether to give the heart to a person who may not be able to take care of it. Bennett, who was in end-stage heart failure and nearing the end of his life, did not qualify for a traditional heart transplant". Prof. Mohiuddin [27]. This was the only available option, at that time, for the patient because he had been deemed ineligible for a conventional heart transplant at UMMC as well as at several other leading transplant centers that reviewed his medical records [UMSOM]. Just when it seemed he had no hope, Mr. Bennett was approached with an unusual offer of a genetically modified pig heart. The idea of a "porcine donation" was not something new for him. Bennett's son said his father had received one porcine heart valve about a decade ago [24]. Before consenting to receive the transplant, Bennett was fully informed of the procedure's risks, and that the procedure was experimental with unknown risks and benefits. Fed up from being hospitalized and bedridden for the past few months, he said "It was either die or do this transplant. I want to live. I know it's a shot in the dark, but it's my last choice. I look forward to getting out of bed after I recover". According to Bennett's son his father" realized the magnitude of what was done and he really realized the importance of it. Of note, Griffith had transplanted pig hearts into about 50 baboons over five years, before offering the option to Bennett [28].

How was Pig's Heart Humanized?

"The ideal method would be to transplant in man organs of animals easy to secure and operate on, such as hogs, for instance. But it would in all probability be necessary to immunize organs of the hog against the human serum. The future of transplantation of organs for therapeutic purposes depends on the feasibility of hetero [xeno] transplantation". Alexis Carrel (1873-1944) -Nobel Laureate

According to David Cooper [29], Carrel was clearly "a man of vision" who wrote prophetic words in 1907. The genetically modified pig heart, used in Bennett's case, underwent 10 genetic modifications, knocked down 3 immune-rejection-related genes, and inserted 6 human genes and 1 growth gene for inactivation to control the size of the heart, which was provided to UMSOM by "Revivicor", a regenerative medicine company based in Blacksburg, Virginia (USA) [17].

Expanded-Access Investigational Experimental Surgery

"It's easy to sit back and be negative when a new treatment is announced. If we all were afraid to attempt the untried, we would have no new treatments", John Collins, Chief of Cardiac Surgery at Brigham and Women's Hospital in Boston [30]. On December 20,2021, an application for expanded access authorization, using a "multi-gene" pig heart with ten gene edits for human transplantation, was submitted to FDA. On December 31, 2021, the authorization was granted under "Expanded Access Compassionate Use Program". The program is "a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available" [31].

Lawrence Faucette: The Second Porcine Heart Transplant Recipient:

"We are once again offering a dying patient a shot at a longer life, and we are incredibly grateful to Mr. Faucette for his bravery and willingness to help advance our knowledge of this field. We are hopeful that he will get home soon to enjoy more time with his wife and the rest of his loving family." Prof. Bartley P. Griffith [32]. The world's second patient Lawrence Faucette 58years underwent xenotransplantation with a genetically modified pig heart, on September 20, 2023. The procedure was carried out at University of Maryland School of Medicine (UMSOM). The groundbreaking transplant team (Prof. Bartley P. Griffith and Prof. Muhammad Mansoor Mohiuddin) was the same which pioneered the the first historic procedure on January 7, 2022.Mr. Faucette, a case of terminal heart disease, was deemed ineligible for a traditional transplant with a human heart, by UMMC and several other leading transplant centers. On September 15, the FDA had granted emergency approval for the surgery via "Expanded Access Compassionate Use Program", in the hope of saving the patient's life. Before consenting to receive the transplant, Mr. Faucette was fully informed of the procedure's risks, and that the procedure was experimental with unknown risks and benefits. He underwent a psychiatric evaluation and met with a medical ethicist, social workers and other members of the UMMC care team to discuss the anticipated risks and benefits and to obtain his informed consent. "My only real hope left is to go with the pig heart, the xenotransplant," said Mr. Faucette during an interview from his hospital room a few days before his surgery. "Dr. Griffith, Dr. Mohiuddin and their entire staff have been incredible, but nobody knows from this point forward. At least now I have hope, and I have a chance." To begin with, Mr. Faucette had made significant progress after his surgery, engaging in physical therapy, spending time with family members, and playing cards with his wife. However, with passage of time his heart began to show initial signs of rejection and ultimately, he succumbed on October 30, 2023.In Memoriam of Mr. Faucette, Prof. Griffith said "We mourn the

loss of Mr. Faucette, a remarkable patient, scientist, Navy veteran, and family man who just wanted a little more time to spend with his loving wife, sons, and family. [32]. Prof. Mohiuddin said: "Mr. Faucette was a scientist who not only read and interpreted his own biopsies but who understood the important contribution he was making in advancing this field. As with the first patient, David Bennett, Sr., we intend to conduct an extensive analysis to identify factors that can be prevented in future transplants; this will allow us to continue to move forward and educate our colleagues in the field on our experience" [33].

Conclusion

"There can be no contentment but in proceeding. "Thomas Hobbes (1588-1679)—English Philosopher.

Although the xenotransplantation neither aims nor can replace allotransplantation, the Xenografts have been considered as a potential alternative to allografts. Whereas heart transplantation stands as a life-saving intervention for those with end-stage heart disease, the genetically modified porcine heart xenotransplantation has become a promising solution to alleviate sufferings related organ failure and improving quality of life. Whereas, the last wish of Mr. Faucette, according to Prof. Griffith: "was for us to make the most of what we have learned from our experience, so others may be guaranteed a chance for a new heart when a human organ is unavailable", the unremitting journey, backed by creativity, courage and determination continues. As rightly said by Dr. Joseph Murray, Pioneer of the First Organ Transplant, "The Surgeons, by nature, tend to be optimists".

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