PERSPECTIVE

Application of the innovation approach to a floyd type I tracheal agenesis case with success

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ABSTRACT

BACKGROUND: The act of introducing a new product, idea, or technique falls within the broad definition of innovation. Innovation is the foundation of the surgical profession, reinventing equipment, research, and technology to enhance patient care. The technique can also be employed on orphan pathologies with no obvious remedies, even though most new therapies are directed towards issues with a sizable patient population. We describe a case of tracheal agenesis, a rare congenital defect with a high mortality and few effective treatments, that benefited from the innovation process and survived without using a ventilator at age three.

METHODS: The parameters of the clinical problem were identified, previous solutions and existing technologies were analyzed, newly invented solutions were brainstormed, value analysis of the potential solutions was carried out Using crowd wisdom and the chosen solution was prototyped and tested using 3D modeling, iterative testing on 3D prints of actual-sized patient parts, and a crowdsourcing platform.

CONCLUSION: Our team was given the direction and necessary steps by the innovation process to create an innovative device for the successful management of an infant survivor with Floyd Type I tracheal agenesis.

Key Words: *Process for innovation; Agenesis of the trachea; Innovation in surgery; Needs identification; Paediatric surgery*

INTRODUCTION

The act of introducing a new product, idea, or procedure that needs creation and implementation is generally referred to as innovation. Teams can uncover unmet clinical needs, develop solutions, and put ideas into action using this iterative process. The practise of surgery is based on ongoing innovation, which has revolutionized science, technology, and equipment to enhance patient care. The Stanford Bio design Fellowship Program, which makes use of the innovation process, has as its specific focus the development of medical devices, which is an important aspect of the practise of medicine.

Iterations can be taken at any moment to improve the solution, and the innovation process should be built on a participatory design approach where the end users are involved from the start to the finish. This procedure begins by determining a need, also known as the needs-finding phase. The next step is to create a need statement, which summarises the clinical issue that has been discovered, the particular demographic affected by the issue, and a quantifiable result that could be impacted by proposed remedies. If there are several needs, a screening procedure is used to determine the primary requirement. The clinical impact of the need, the level of pathophysiology comprehension, consideration of current and emerging clinical approaches, and a preliminary assessment of the market potential for a solution to this need are all filters in the screening process. However, in this case, the focus was on the availability of alternative solutions rather than the marketability of the proposed solution.

The team can start the invention, or design, phase once a clear needs statement has been established. Several potential solutions are discussed during brainstorming sessions. The team must narrow the list of viable solutions by factoring in things like legal frameworks, possibility for reimbursement, technological viability, and the viability of the model required to deliver the solution to the patients. To learn about these factors for each proposed solution, research is frequently required. The creation of alternate designs for comparison follows. The team then starts creating and designing the best ideas, which frequently calls for several iterations of prototypes for each concept.

Implementation is the last stage of the innovation process. Planning for clinical, regulatory, reimbursement, marketing, and sales strategies is necessary for many medical devices or solutions. Finally, licence or

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regulatory permission will need to be secured. Funding sources may need to be looked into.

We describe a case of tracheal agenesis, a rare congenital defect with a high mortality and few effective treatments that benefited from the innovation process and survived without using a ventilator at age three.

METHOD

The dimensions of the clinical problem were determined, and prior solutions were examined, using the Innovation Process framework similar to the Stanford Bio design Program. Wisdom of the crowd, or the collective judgment of a group of people rather than that of a single expert, was used to conduct value analysis of the potential solutions using existing applicable technologies and freshly devised solutions that were gathered, compared, and collated. In order to accomplish this, a panel of experts from various clinical disciplines, engineers with innovation experience, and business leaders were given a thorough description of the solutions along with their benefits and drawbacks, and their opinions were then solicited via an email survey. Based on their background in innovation or entrepreneurship, the experts on this panel were chosen. In situations where there are many potential solutions, the core team in charge of the project will choose which ones to drop from the list using the design criteria for the issue. The winning proposal was chosen, then it was prototyped, tested, and evaluated utilizing 3D modeling and 3D prints of real patient parts. After receiving regulatory permission from the FDA, Department of Health, IRB, family approval, and hospital approval, the stent was implanted in the patient.

RESULTS

Phase of clinical problem identification

Our patient was a 35-year-old woman who gave birth to a term, 3.6-kg girl with little prenatal treatment. The infant was given the diagnosis of tracheal agenesis within the first week of life after a bronchoscopy revealed a trachea esophageal opening in the mid-esophagus connected to confluent main stem bronchi. Additional research also revealed hemi vertebrae, a right choroid plexus cyst, and a complete atria-ventricular canal defect. In order to save their child's life, the parents voiced a great desire to do so. Reconstruction of the patient's airway was required. On the patient's third day of life, a gastrostomy tube was placed, and on the patient's eighth day of life, a duodena, jejunostomy and Ladd surgery for duodenal blockage and malrotation were performed. On DOL 15, the patient underwent upper esophageal division, with the middle esophagus externalized as a stoma above the sternal notch, which was intubated with an extended tracheostomy tube. The upper esophagus was diverted to a right cervical esophagostomy.

Phase of invention or design

Using value benefit analysis, potential solutions utilizing current technologies were investigated and contrasted. Crowd wisdom-based decision making was used to discuss and reach an agreement on 3D printing and preoperative planning. The primary option chosen was a 3-D printed external splint made of PCL material, which will degrade after three years and allow the airway to grow.

A life-sized 3D-printed model of the patient's thorax and its internal organs was created to evaluate our suggested fix. The airway esophagostomy or endotracheal was printed in multiple copies to enable testing. On the 3D models, various iterations of the suggested esophagotracheoplasty were also tried. On the models, the fit of various sizes of the 3D-printed PCL splints was evaluated. Testing showed that the 3D-printed splints fit well over the esophagotracheoplasty.

Phase of implementation

The US Food and Drug Administration under expanded access, the Pennsylvania Department of Health, the Penn State University Institutional Review Board, family permission, and hospital approval all provided their regulatory clearance.

The patient was now ready for final airway repair with our 3D-printed external bio-resource able splint at the age of five months. She had esophago tracheoplasty, tracheoesophageal fistula resection, and stent implantation for external esophageal airway support.

DISCUSSION

The innovation process is centre on assembling interdisciplinary teams to recognize unmet clinical requirements, come up with fresh solutions, and put the concepts into practise. The innovation process can be used in a number of clinical settings, such as paediatric surgery, where some uncommon disorders might benefit from a cutting-edge treatment. The technique can also be employed on orphan pathologies with no obvious remedies, even though most new therapies are directed towards issues with a sizable patient population. Less than 1 in 50,000 live newborns experience the rare and often deadly congenital abnormality known as tracheal agenesis. There have been 150 cases reported in the literature, and they are all almost always fatal. Esophageal connection with the trachea or major bronchi is often linked to tracheal agenesis. There aren't many effective airway reconstruction techniques that have been documented in the literature. The parents expressed a strong desire to pursue potential lifesaving measures for their child despite the illustrated grim prognosis that was anticipated.

Our team started with a screening and research phase before coming up with potential solutions for our needs statement. An inventor may feel compelled to start inventing right away if they have discovered one or more compelling needs. To validate any demand and comprehend how it might be met, it is essential to gain a thorough grasp of the pertinent disease condition, with an emphasis on its mechanism of action. The literature on tracheal agenesis, including its anatomy and physiology, pathophysiology, symptoms, results, and epidemiology, was thoroughly reviewed by our team.

Only seven cases of this disease have been documented in Asia and one in the rest of the world, it was identified during this exploratory period. All of the survivors—all but two—were fitted with external splints. They often pass away as a result of recurring airway infections and consequences from airway collapse. The determined design parameters that are discussed in our results section are the outcome of this discovery. Additionally, it was during this stage that technologies that are now in use and appropriate for a potential solution were found. The most popular external splint specifically employed by the prior survivors is eptfe grafts. Tracheomalacia and bronchomalacia have been treated successfully with 3D-printed Pcl splints in paediatric patients, including newborns.

There are few effective therapy options for replacing missing esophageal airways in patients with the unusual condition known as

tracheal agenesis.

CONCLUSIONS

It is concluded that by applying the innovation process, these uncommon anomalies can benefit from solutions derived from the tried-and-true framework of careful investigation, iterative design prototyping with investigation-derived design parameters, and final implementation taking necessary regulatory, technical, logistical, financial, and ethical considerations into account. Similar methods have been used at our institution with success in the commercialization of numerous surgical and medical applications for the ideation and implementation of solutions to clinical problems under the direction of our Surgical Innovation Group. In order to address supply chain bottlenecks during the COVID-19 pandemic, a similar procedure was also adopted for emergency use applications. The method is being used for the first time at our institution in the paediatric setting, where orphan disorders are more prone to occur. Even for a dire diagnosis like tracheal agenesis, a successful solution is still feasible with such a framework.