

Innovations – not crossing the red line

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Abstract

Continuous innovations mark progress in the craft of surgery. Throughout history, successes and failures in innovations have raised ethical issues. In this article, I discuss the subject based on my experience as a paediatric cardiac surgeon. I conclude that discussion with peers, openness to criticism, and being mindful of the patient's well-being must be considered while innovating, and these aspects of the 'medical arts' must be discussed and inculcated during medical education.

Innovations are an integral part of science and the field of medicine is no exception. Additionally, the field of surgery -- and more so paediatric cardiac surgery -- has its unique set of challenges. Paediatric cardiac surgery represents, perhaps, the toughest of the surgical specialties given that it deals with babies. The young age of the speciality itself (roughly four decades), the ever increasing dependence on advanced technology, the fact that the lives of children are involved, and the ambiguity in ethical standards make our profession particularly challenging.

The field of paediatric cardiac surgery is replete with examples of innovation, as well as of courage and sensitivity, born out of deep caring for the "blue baby". Many of these innovations, dating back to the late 1930s, started off as failures or aborted attempts associated with much morbidity and mortality. The failed attempt by Streider at ligation of a patent ductus arteriosus and the reportedly "surreptitious" successful operation of the same type the very next year by Gross when his chief was away on vacation (1) drive this point home.

However, the most remarkable example of pioneering effort is the description of the Blalock-Taussig shunt. Taussig and Blalock went to extraordinary lengths to test their hypothesis in the treatment of tetralogy of fallot on animal models and performed the first surgery on an extremely sick child who had a poor prognosis. The aftermath of this procedure is a saga of cooperation and education of all concerned in the spread of the knowledge and skills of paediatric cardiac surgery. The surgical and the medical cardiology teams involved in the BT shunt operations willingly gave their time for talks at medical and surgical meetings and accommodated the many doctors who came to observe the coordination of paediatric cardiac and surgical care. Dr Taussig analysed not only the many successes of the operations but also their failures and Dr Blalock received these as valuable learning information. This cooperative model is the recipe for successful paediatric cardiac care teams all over the world today.

In this article, I present a personal example to discuss the various scientific, ethical, and emotional issues that innovation presents for the surgeon.

I still remember, sadly but vividly, a child who had a complex form of tetralogy of fallot. This was around 1995. We had read an authoritative European article that described a technique in which total correction of the malformed heart had been performed. We were greatly impressed with the technique and its success since it corrected the complex problem without using a conduit, thereby reducing morbidity and costs. However, our surgery was unsuccessful and we lost the child. Looking back, we realised the flaws in the technique. But the loss was irreplaceable for all of us. Several incidents like this have repeatedly made us realise that often complications arise due to our lack of complete knowledge of the child.

Though application of a new technique, or improvement on an old technique while performing surgery, is a necessity, an unexpected failure can mean a loss of life. Given the number of variables in each child, whether an improvisation or innovation was necessary in a particular child with a congenital heart defect is a difficult question to answer. This is especially so when one is contemplating the improvisation during the course of the operation. Any delay between conceptualisation and execution would result in increasing the time of cardio-pulmonary bypass and the cross clamp time. This would directly affect the morbidity and risk to the life of the child. At the same time, denial of that improvisation/innovation would amount to denial of appropriate and precise care to the child.

The following text represents the sum of my thoughts concerning the dilemmas we face as surgeons in our professional lives. My colleague, a paediatric cardiologist, brought to me a family with a four-month-old child. The child was rather underweight and was breathing quite fast. Her chest was prominent. The family had come to our centre in South India all the way from Gujarat. Despite the tiresome journey, the parents' anxiety and apprehensions concerning their precious baby were very evident. They were devastated to learn that their child had a serious heart problem that required a complex surgery.

Alien to the culture, customs, food habits and language of the southern Indian city, they had arrived in the fond hope that we were going to treat the problem as we were considered experts in this field. Unfortunately, what they did not know was that science itself had not mastered this unique problem. The abnormal communication between the left and right hearts (cardiac type of total anomalous pulmonary venous connection, with severe obstruction at the vertical vein to

coronary sinus junction) was further complicated by the narrowness of the communication that was at the back of the heart. It was considered an extremely dangerous area that was close to the coronary arteries and inaccessible. While we had acquired the knowledge to address the connection, we had not learnt to increase the size of the connection and that was going to be the deciding factor in long-term success as more than half of such children would have, to a large extent, persistent residual problems. The disastrous consequences for the last child operated on by my colleague were still fresh in my mind. I knew we had to sort this out. The idea that we had to do something in addition to the conventional technique kept coming back to me repeatedly, over the next two days till surgery. During the operation, we had to find a solution that eliminated this narrowing. We admitted the child and we performed all the necessary preoperative tests.

That necessity is the mother of invention actually struck me on the day of surgery while I was preparing to leave for the hospital. Soon after I reached the hospital, I tried discussing this with my team members. Most of them, except for my colleague who had brought the family to me, could not comprehend that I could actually fix the problem with the improvisation I had thought of. But, we worried about the potential haemorrhage if this solution were tried. The sole supporter of this venture was my cardiology colleague, a person of impeccable character and integrity. That gave me the necessary courage to venture into the uncharted territory. My other colleagues' concerns were genuine and their reluctance to endorse this surgical improvisation was understandable, given the complex surgery and the element of uncertainty in doing something new and untested. However, to me, my cardiologist's firm belief in our approach and my own conviction were far more overpowering.

I discussed the complexity of the situation with the parents, to the best extent possible and they -- as is always the case -- left it to our wisdom.

We performed the surgery with a plan outlined in my mind and the child did exceedingly well. We published the case in a prestigious journal (2) and now it has become a standard operation for this complex surgery. In fact, we won many accolades for this as we presented our experience at major international conferences. Now, every time I see this wonderful child (now attending school) on follow-up, I feel exhilarated that our idea helped us address one of the most important and complex problems in congenital heart surgery.

This incident illustrates the success of an idea that germinated out of necessity but lacked support of prior clinical experience. I have wondered several times, as we keep innovating in our specialty, whether we did right to apply these untested ideas to clinical settings. Apart from my conviction and reason, what else had I to support the experiment? My colleague's support, a widened knowledge base, the prevailing imperfect treatment, the fact that the child's family was not very enlightened about the treatment, or the plain and simple fact that the child could not disagree with me? How does the law of the land react to this? Perhaps none of us has satisfying answers to the questions

I have raised. More importantly, my conscience continues to ask me whether it was correct on my part to have done that.

No red line exists that distinguishes innovation from misadventure. The consequence of our actions -- either benefitting the child or endangering it -- defines it one way or the other. Did we abuse faith, and confuse lack of accountability with the opportunity to innovate? On the other hand, let us also acknowledge that, for science to progress, it needs to evolve and move beyond time-tested paradigms. This warrants scrutiny in our field as it is very young and still evolving, unlike other medical specialities.

If I look back at my own experiences, I think I developed conviction not only from my own knowledge base but also from the terrific faith and confidence of my cardiology colleagues and other peers in my ability to convert ideas into action. Critics and colleagues participated in improving and implementing the idea. I think being transparent, ethical and communicative while maintaining a sound knowledge base helped my situation. Perhaps there lies the solution to the dilemma we face. What we do or do not do should have the sanction of our colleagues and peers. Discussing with them not only raises the possibility of acceptance of our efforts but may also refine the idea further. The most ardent critic of our ideas perhaps unknowingly becomes the biggest supporter of our endeavour and the saviour of the patient as criticism draws out the flaws in ideas. That applies more in my field than in any other speciality in medicine. I have never ceased to learn from the frailties and challenges of my profession.

The partnership of courage and conviction is vital to the development and conversion of an idea into action. In my opinion, courage is required, not just as "grace under pressure" but as a necessary attribute. The surgeon is faced with significant challenge and dilemma as his /her reputation and character are at stake while executing the idea. There have been instances in the history of medicine where one unsuccessful act ruined the doctor's career. This is probably the reason that few failures are published.

I am making this statement on the basis of a series of innovations that we published (3, 4) which several others have reproduced. We draw redemption from it. Finally, that is what vindicates our claim.

As John Gribbin stated in his book *Science: a history*, "Scientific progress has been made in the most part by ordinary clever people building step-by-step from the work of their predecessors" (5).

Let us also not forget that in the process we also helped science take small steps to be better for the next child with a similar problem. When we are unsuccessful in our endeavour, we end up learning, as a team -- albeit at a great cost -- and it is important that we do not repeat the errors. That is where our character and integrity as responsible doctors are tested. I must however confess that the awareness of our responsibility continues to grow as we become seniors in our field and I wish those qualities had come to me earlier.

We live in a world that is becoming too ready to litigate – and where healthcare is expensive and presents a large number of choices. All those children's cases in which we tried our innovative ideas represented a challenge to existing and universally accepted treatments. But each time we toy with a new idea, we need to ask whether it conforms to the framework of ethical and legal behaviour. Failure in our attempts to convert an idea into a successful action does not achieve the desired objective of progress in science; it also means that our idea was flawed. Moreover it endangers a life. Hence these errors need to be addressed if further mishaps and loss of lives are to be prevented.

Dissatisfaction with the inadequate and curiosity to innovate may be innate to the few. Maybe it can be inculcated in others by inspired teachers. But the great responsibility that comes with this -- of being able to keep the interests of the patient foremost, not personal glory, not even the progress of science -- requires the qualities of honesty, openness, willingness to share and discuss ideas, as well as the ability to give and take criticism, and accept failure with grace.

Our current medical education does not prepare us for this.

Perhaps early and continuous exposure during medical school training to the history of medicine, medical ethics and western and Indian literature with an undercurrent of these ideas will go some way towards preparing students. Medical teachers who are role models will have a huge impact in propagating these qualities among generations of students and doctors.

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Contemplating complications: living the experience, learning the lessons

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Abstract

Complications related to the use of new diagnostic and therapeutic techniques are inherent to innovation in medicine. Appropriate consent should be obtained before subjecting patients to these techniques. In spite of doing this, when a complication does occur, one can easily relate to its devastating impact on the patient and his/her relatives. The toll that such events take on the treating physician also needs to be considered. The burden of conscience when a patient consents to such a procedure with implicit faith in the physician is immense.

A case of irreversible paraplegia due to non-target embolisation of the anterior spinal artery in a young lady undergoing bronchial artery embolisation for hemoptysis is discussed. A feeling of "sadness and guilt" and a scientific analysis of the cause for the adverse event result in changing the protocol of the procedure leading to increased safety for future patients. Wide consultation with colleagues and help from institutional review boards are useful in assuring the treating physician about the justification of performing such procedures and help in coping should complications occur.

The manner in which these events are managed, especially by medical teachers in teaching hospitals, is an important learning point for medical students and doctors in training. The need for appropriate open forums in institutions is emphasised, where such events are shared by physicians, resulting in unburdening themselves and potentially in education for all present.

Background

In 1982-83, my colleagues and I at the Department of Radiology, KEM Hospital, in Mumbai, started performing bronchial artery embolisations (BAE) for the treatment of massive haemoptysis, ie blood in the sputum, due to pulmonary tuberculosis. I had read the literature around this and realised that performing bronchial artery embolisation was fairly straightforward and could be done with the instruments, equipment and skill we had.

Before each intervention, we would explain the procedure to the patient. We mentioned the usual complications associated with femoral catheterisation. We added that if the procedure failed, we might have to redo it and if even that failed, an operation might be needed to remove the affected lung. From my reading of the literature, I did not think that any other complication was common enough to merit explanation to the patient or the patient's family. As many of these patients had presented to us in the emergency, and most patients were deeply disturbed by the hemoptysis, almost all patients readily consented to undergo the procedure.

In a couple of months, we had successfully embolised and treated about half a dozen of these patients with good results and without incident.

At this time, we let our resident doctors perform these procedures under our supervision (I was a lecturer then). This went on for a few months and the procedure became a standard of care at our hospital.