REVIEW ARTICLE

Pediatric cardiac interventions: Innovations from India

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ABSTRACT

India, owing to its population structure, faces an enormous burden of children born with congenital heart disease (CHD). Systematic challenges such as limited public health infrastructure, a shortage of trained specialists, and high out-of-pocket expenditures hinder uniform access to comprehensive CHD care. Despite these limitations, Indian pediatric cardiologists have delivered innovative and often cost-effective solutions to challenging clinical problems. Indigenous devices such as the MyVal transcatheter heart valve, Konar-MF (multifunction) occluder, and Zephyr large-diameter stents are significant achievements in their respective fields. Static balloon dilatation of interatrial septum and balloon-assisted atrial septal defect (ASD) device implantation are prime examples of many innovations that were established by Indians and followed across the world. India also helped consolidate significant interventions in children, such as percutaneous transvenous mitral commissurotomy and interventions for aortoarteritis. Notably, Indian centers have published some of the largest series on transcatheter closure of sinus venosus ASD and ruptured sinus of Valsalva aneurysm. Close collaboration with adult coronary interventionalists has facilitated innovations borrowed from coronary chronic total occlusion hardware and techniques to recanalize ductus arteriosus or membranous-type pulmonary atresia. This manuscript discusses some of India's innovative contributions to the field of pediatric cardiac interventions.

Keywords: ASD device closure, children, device closure, Konar MF device, MyVal transcatheter heart valve

INTRODUCTION

Each year, more than 200,000 infants are born in India with congenital heart disease (CHD), with approximately one-fifth suffering from severe defects that require early intervention.[1] Approximately 300 pediatric cardiologists work in a handful of tertiary centers, and the most populous states (Uttar Pradesh and Bihar) have limited access to comprehensive management of sick infants.[2] The healthcare system in India has improved tremendously in the last couple of decades, with a particular focus on "Make in India" and "Atmanirbhar Bharat Abhiyan" (a self-reliant Indian initiative by the government of India).[3] In previous issues of the Annals, we discussed the growth of interventional pediatric cardiology in general and the need for appropriate regulations in India.[4,5] This manuscript highlights some of the innovations from India in the field of pediatric cardiac interventions [Table 1]. The methodology used and the disclaimer are described in Appendix 1.

Indian pediatric cardiologists have delivered several innovative and often cost-effective solutions to challenging clinical problems despite the shortage of resources and many socioeconomic barriers. The core principles of providing quality care to as many infants with CHD as possible with limited resources encourage frugal innovations. "Necessity is the mother of invention." The challenges many centers face in procuring specific hardware tailored for pediatric interventions at a

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Table 1: Selected list of innovative pediatric cardiac interventions from India

New devices from India (or by Indians)
MyVal Pulmo
Konar MFO
Zephyr - stent/covered stent
Python BZ sheath
New techniques
Practice changing techniques for difficult but common scenarios
Balloon-assisted ASD device deployment
Retroflection of the TEE probe for viewing the IVC rim
Various techniques for the closure of multiple ASDs
Ductal stents for retraining the left ventricle in TGA
CTO hardware for pulmonary atresia
Emerging solutions to purely surgical subsets
Sinus venosus ASD covered stent
Percutaneous Fontan completion
Percutaneous Fontan fenestration creation
RVOT alcohol ablation
Interventions standardized/consolidated by India
PTMC in rheumatic mitral stenosis
Perimembranous VSD device closure
Interventions in aortoarteritis
RSOV device closure
Existing techniques/devices used for newer indications
Coil for PDA closure
ADO II for VSD closure
AVP II and muscular VSD devices for difficult PDAs
Innovative emergency bailouts
RVOT stenting during a cyanotic spell
Manual autotransfusion for on-table spell
Balloon/stenting of obstructed TAPVC

MFO: Multifunction occluder, ASD: Atrial septal defect, TEE: Transoesophageal echocardiography, IVC: Inferior vena cava, TGA: Transposition of great arteries, CTO: Chronic total occlusion, RVOT: Right ventricular outflow tract, PTMC: Percutaneous transvenous mitral commissurotomy, VSD: Ventricular septal defect, RSOV: Ruptured sinus of Valsalva, ADO: Amplatzer duct occluder, AVP: Amplatzer vascular plugs, PDA: Patent ductus arteriosus, TAPVC: Total anomalous pulmonary venous connection

reasonable cost are extremely important enablers. Many innovations have become necessary since procedural failure is not an option in privately funded hospitals in low- and middle-income countries (LMICs). The existence of closer collaboration with our adult colleagues and the sharing of cath labs have been significant factors in finding innovative solutions.

MAJOR DEVICES MADE IN INDIA (OR BY INDIANS)

MyVal Transcatheter heart valve for dysfunctional right ventricular outflow tract

MyVal transcatheter heart valve (THV), a "made in India" product designed by Meril Life Sciences Pvt. Ltd (Vapi, India), represents a landmark Indian success in the percutaneous management of valvular heart diseases. Initially developed for treating severe aortic stenosis in the elderly, it offered several advantages over other contemporary valves, including the 1.5 mm increments in sizes (instead of 3 mm) and the availability of 35 mm THV for large annuli. Recent data established MyVal THV's noninferiority to other THV systems such as Sapien (Edwards Lifesciences, Irvine, CA, USA) and Evolut (Medtronic, Minneapolis, MN, USA) in the aortic position.[6] These features made MyVal an attractive option for treating dysfunctional right ventricular outflow tracts (RVOT) in various operated CHD cases. It was first reported from India in seven patients in a small multicentric study.[7] Sivaprakasam *et al.* also reported the successful use of MyVal (up to 32 mm size) in dilated native/patched RVOTs.[8] Such patients with dilated native RVOTs were not suitable for conventional THV systems designed for transcatheter pulmonary valve implantation (TPVI) and would often be sent for repeat surgeries. A recent publication describes a multicenter experience of TPVI with MyVal from centers outside India in patients with dysfunctional RVOTs. TPVI with MyVal was performed in 53 patients with a median age of 15 years with 100% procedural success. At 1-year follow-up, the results of TPVI were excellent, and only 3 patients had moderate pulmonary regurgitation.[9] This issue reports the first successful use of 35 mm MyVal THV for a dilated native dysfunctional RVOT.[10] Meril Lifesciences has launched a dedicated THV and delivery system for the pulmonary position (MyVal Pulmo THV system). However, affordability issues and the lack of data on long-term durability remain the primary concerns.[11]

Python BZ sheath

This large bore sheath ranges from 14F to 26F and can be tracked over multiple guidewires, unlike conventional sheaths, which are tracked over a single guidewire. Tracking large and long sheaths over one guidewire through the right ventricular inflow and then the outflow is technically challenging and often leads to procedural failure. This sheath features a dilator with three-holed tips, each accommodating one 0.035" guidewire, significantly increasing trackability. In addition, the dilator includes a hemaquit valve, in addition to the sheath's valve, to prevent bleeding from the rear end of the dilator, whereas the sheath is being tracked over multiple wires. This innovative concept recently received a US patent (Patent No. US12,011,559 B2, dated June 18, 2024) and has been marketed by Meril Lifesciences since last month.

Konar MF occluder

Konar-MF (multifunction) occluder, a device named after an Indian, may represent a milestone in the percutaneous closure of ventricular septal defect (VSD). Konar-MF occluder offers several structural advantages such as low-profile (requires 4–7 Fr delivery sheath), flexible waist made from soft-woven nitinol wires with high conformability to the shape of the septal defect, screwing mechanism on both sides (can be delivered antegrade or retrograde) as well as reduced clamping force/stress on margins of the ventricular septum. Multiple studies have

reported the safety and efficacy of Konar-MF occluder for the closure of perimembranous as well as muscular VSDs using either an antegrade or retrograde approach.[12-15] The incidence of complete heart block seems to be lower with this device.

Genuinely multifunctional, the Konar-MF device has also been utilized in percutaneous closure of patent ductus arteriosus (PDA) with unusual morphology, aorto-pulmonary window, Gerbode defect, and coronary fistula.[16,17] A recent report in this journal describes the use of Konar-MF in closing an aortopulmonary window in a critically sick 1.35 kg premature infant.[18]

Zephyr stent

The availability of large vessel stents capable of redilation to larger diameters remains a challenge for pediatric interventional cardiologists. An Indian-made cobalt chromium stent, the Zephyr stent (Sahajanand Laser Technologies, Gujarat, India), provided the much-needed alternative. It is available in three sizes: L (up to 18 mm), XL (up to 26 mm), and XXL (up to 32 mm). The first-in-man Indian study proved its role in 22 patients in varied indications.[19] Subsequent modifications included adding a polytetrafluoroethylene cover, making it suitable for countering vessel rupture.[20] Its utility has reached novel indications, including transcatheter Fontan completion.[21]

CONSOLIDATING EVIDENCE FOR THE EFFICACY OF INTERVENTIONS

Rheumatic heart disease and juvenile mitral stenosis continue to be significant healthcare concerns among children in India.[22] A few studies from India established the efficacy and outcome of percutaneous transvenous mitral commissurotomy (PTMC) in children with juvenile mitral stenosis using the Inoue balloon,[23-25] even during an episode of rheumatic fever.[26]

Nonspecific aortoarteritis is another disease encountered in Indian children with very different clinical presentations, and many children would require interventions.[27] Some large series on interventions in children with Takayasu arteritis are from India.[27-29]

There are also descriptions of device closure of congenital portosystemic shunts[30] and recanalization and stenting in Budd Chiari syndrome from Indian centers, reflecting the expertise provided in the field of structural interventions.[31]

Percutaneous management of sinus venosus atrial septal defects

Superior sinus venosus (SV) atrial septal defects (ASDs) have been managed exclusively by surgical patch closure. Various centers have used a covered stent in the right superior vena cava to close SV ASD percutaneously, with the first report of percutaneous closure from an Indian center in 2014.[32] Over the last few years, a few Indians have mastered closing SV ASDs percutaneously and have described various innovative techniques.[33] A large series of transcatheter management of SV-ASD is reported by Sivakumar *et al.*, who described balloon interrogation of the cavoatrial junction to confirm the occlusion of the defect without compromising the flow of the right upper pulmonary vein (RUPV).[34] The same investigators recently published their experience of covered stent exclusion of superior SV-ASD in 100 patients with an overall procedural success rate of 97%.[35] They also describe certain procedural modifications for improved success rate, including trans-septal RUPV protection, use of semicompliant balloons for interrogation, overlapping stents, and avoiding venovenous circuits. Further advancements have enabled even contrast-free transesophageal echocardiography-guided closure in a patient with advanced kidney disease.,[36] handling innominate vein occlusion using innovative techniques,[37] use of self-expanding stents,[38] and a detailed understanding of the mechanisms of residual left-to-right shunt and offering different solutions.[39] However, strict case selection, a heart-team approach, and informed decisions are critical in the optimal utilization of such emerging technologies in practice.

INNOVATIONS IN ESTABLISHED INTERVENTIONS

Percutaneous closure of complex atrial septal defects

In the device closure of large ASDs, repeated left atrial disc prolapse into the right atrium often frustrates operators. Dalvi *et al.* described a novel way to circumvent this problem using a balloon-assisted technique (BAT) to deploy ASD devices,[40] which was further substantiated by many reports,[41] and is an established technique worldwide.

Significant publications from India standardized the transesophageal echocardiographic echocardiography (TEE) imaging of an ASD and the naming of the rims.[42,43] Another novel work describes a better technique to visualize the inferior vena cava rim using retroflection of the TEE probe.[44] Pavithran and Sivakumar have described an innovative precautionary technique for patients with deficient rims. In this technique, the operators pass a snare through the delivery sheath after the device has been placed but has not yet been released.[45] If the final position of the device is unstable, impending embolization of the device can be prevented by recapturing the device using the same snare.

A large Indian series (n = 87) describes the successful transcatheter deployment of a 40 mm ASD device delivered by BAT,[46] with the largest reported being a custom-made 48 mm device.[47] While device closure of ASDs >20 mm in small children is generally not recommended, we do have emerging data on the safety of this procedure, even in this subset of patients.[48] ASD device closure under conscious sedation and transthoracic echocardiographic guidance is feasible and safe even in small children weighing <10 kg, as demonstrated in a recent large series from India.[49] The optimum strategy for closing multiple ASDs is not clear. Balloon interrogation of the septum intervening between two separate ASDs for decision-making[50] and a large series of using multiple septal occluders have been reported from India.[51]

In addition, India has developed Indigenous ASD devices designed by various organizations, including the Sree Chitra Thirunal Institute of Medical Science and Technology and Meril Lifesciences, which could reduce the cost of the procedure.

Percutaneous closure of ventricular septal defect

Transcatheter device closure of VSD was performed as early as 1999 in India,[52] using a Rashkind double umbrella device and Amplatzer ventricular septal occluder in a large series of patients.[53] The conventional antegrade or arteriovenous looping technique for VSD device closure involves difficult catheter manipulations, prolonged procedural times, and possible excess injury to the cardiac conduction system. A few publications from India describe a novel retrograde technique of perimembranous VSD device closure.[54] Another novel technique of VSD device closure that eliminates the need for arteriovenous loop creation was described by Koneti *et al.*, in which the operators used Amplatzer Duct Occluder (ADO) II delivered through a Judkins right catheter to close perimembranous or muscular VSD in 13 children.[55] The same team also reported transfemoral, transinteratrial septal closure of muscular VSDs in 9 young infants (median age 6 months) using an Amplatzer muscular VSD device or ADO II.[56] The first device closure of a Gerbode defect was from India in 2006.[57] There are also rare reports of device closure of VSD at subpulmonic locations, otherwise considered unsuitable for percutaneous closure.[58]

Patent ductus arteriosus device closure

Device closure of PDA is an established procedure. Dalvi *et al.* described a technique of temporary balloon occlusion-assisted delivery of Gianturco coils for closing PDAs.[59] Subsequently, Kumar *et al.* described a novel method for the closure of large PDAs using bioptome-assisted coil delivery.[60] The same group later described bioptome-assisted coil delivery in moderate-large PDAs (>3 mm) in 86 infants and small children with <10 kg body weight.[61] Transcatheter closure of PDA using coils has also been described in low-birth-weight preterm infants.[62] This approach represents a cheaper alternative; however, with the availability of low-cost, affordable devices, coil occlusion of PDA is almost given up. Elongated PDAs are unsuitable for device closure with ADO I or ADO II; a study from India demonstrated the feasibility of closure of such PDAs with Amplatzer vascular plug (AVP II), which has no retention discs.[63] Large PDAs detected in older children may not be amenable to device closure with conventional devices and, hence, are subjected to surgical ligation. A publication from India describes a plausible solution for such patients using custom-made large-size PDA or muscular VSD occluders.[64]

Left to right shunts with severe pulmonary artery hypertension (PAH) are not uncommon in LMICs. Closing shunts with irreversible pulmonary vascular disease have a poor intermediate and long-term outcome as compared to Eisenmenger syndrome. Furthermore, not closing the shunt with reversible PAH can deny these patients improved quality of life and even longevity. A multimodality approach to deciding about the appropriateness of closure in this subset of patients with ASDs and PDAs having severe PAH is documented by a few Indian centers.[65-67] However, long-term follow-up data of carefully selected patients with a control group is essential to define cutoffs and prove the utility of such interventions.

Palliative interventions in tetralogy of Fallot

Infants with Tetralogy of Fallot presenting with severe cyanosis or refractory spells before 6 months of age or those with unsuitable pulmonary arteries undergo palliative surgical shunts (modified Blalock-Taussig-Thomas shunt in most cases). Consequently, several less invasive techniques have been described from India to palliate such infants using catheter-based procedures in resource-limited settings where surgical options are limited and postoperative morbidity and mortality are high. These include balloon pulmonary valvuloplasty in infants with predominant valvular pulmonic stenosis, RVOT stenting, and PDA stenting.[68-70] RVOT stenting has also been used in emergency settings in infants with refractory cyanotic spells.[71] An innovative bail-out method is also described by Kothari *et al.*, where the authors manually autotransfused femoral artery blood into the pulmonary artery (PA) through a 6Fr right coronary catheter while managing a case of on-table refractory spell.[72]

Ruptured sinus of valsalva device closure

Open surgical repair is the traditional management for patients with ruptured sinus of Valsalva (RSOV) aneurysm. Transcatheter RSOV device closure, first described by Cullen in 1994, has also been reported in India with a few

innovative modifications.[73,74] Even a retrograde approach to close RSOV is also described.[75] A concomitant restrictive VSD (especially supracristal VSD) has conventionally been considered a contraindication to device closure. A study from India describes a 92% success rate (12 out of 13 attempted cases) of device closure in patients with concomitant restrictive VSD.[76] A recent series describes RSOV device closure solely under TTE guidance, thereby obviating the need for general anesthesia.[77]

Borrowed from percutaneous coronary interventions

Patients with transposition of great arteries (TGA) often present late in India with regressed left ventricles (LV); the ideal management of such late presenters is unclear. The traditional approach involves retraining the LV through either PA banding or an aortopulmonary shunt, followed by arterial switch operation (ASO), two-stage ASO, or atrial switch operations. Sivakumar *et al.* described PDA stenting as a less-invasive method for retraining LV. After LV was prepared, the ASO was performed as usual, and the PDA stent was removed.[78] PDA stenting has been performed even in totally occluded ducts, using coronary chronic total occlusion (CTO) hardware and techniques.[79] Coronary CTO hardware has also been used as an alternative to radiofrequency energy for perforating the membranous type of pulmonary atresia.[80,81] Such studies highlight the close interaction and learning between pediatric and adult cardiologists with expertise in coronary interventions, another hallmark of pediatric cardiac interventions in India.

In a study from India, high-pressure, noncompliant coronary balloon use in initial dilation of the coarctation segment in neonates and young infants with coarctation of the aorta has been demonstrated to yield superior outcomes.[82] However, the long-term outcomes and comparison with established surgery are desirable before such an approach is taken as the standard of care.

Fontan operation-related interventions

Completing the Fontan operation percutaneously is currently generating significant enthusiasm among Indian interventional pediatric cardiologists.[21] This is another area where case selection will be critical to make the procedure an established intervention. Creating a fenestration is an accepted method to tide over the immediate postoperative period in Fontan operation. Gupta *et al.* describe Inoue balloon-assisted fenestration of extracardiac Gortex conduit in a postoperative Fontan patient with refractory systemic venous congestion.[83] Whenever polytetrafluoroethylene conduits placed many years earlier offered significant challenges for creation of fenestration in failing Fontan circulation, unusual methods of creation of fenestration include puncturing the undersurface of the PA into the left atrium through the transverse sinus of the heart.[84] Restricting an undesirable large fenestration causing severe hypoxemia has been described in India using flow restrictors.[85] A novel redirection technique is also described for directing Fontan flows when unequal hepatic venous blood delivery is offered to the lungs, which are affected by pulmonary arteriovenous malformations.[86]

Miscellaneous congenital heart disease interventions

Balloon atrial septostomy with conventional catheters is usually ineffective beyond neonatal age due to a thickened atrial septum. Shrivastava *et al.* first described static balloon dilatation of the interatrial septum in 1987,[87] which has become an established procedure. Sicker neonates with obstructive total anomalous venous connections may be stabilized preoperatively with balloon dilation of the obstruction.[88]

While transcatheter alcohol septal ablation is an established therapy in hypertrophic cardiomyopathy (HCM), successful alcohol ablation was reported by Ramakrishnan *et al.* in a case of severe infundibular pulmonary stenosis.[89] The authors identified a large conal artery supplying the hypertrophied infundibular muscle bundle and selectively injected absolute alcohol in this target artery to create an iatrogenic infarct, thereby reducing the obstruction to blood flow at the RVOT. Alcohol ablation remains less established in children where surgical myectomy is the preferred choice for symptomatic HCM. Its safety and role in young patients with select indications was described from India on 12 patients with intermediate-term follow-up.[90] Transcatheter closure of the origin of the anomalous coronary artery from the pulmonary end offered an alternative option to left coronary surgical ligation with acceptable intermediate-term follow-up results.[91,92] Small innovations for various procedures, including unusual routes, complex defects to close, and interventions in sicker patients, have been described in a large series using AVPs.[93]

A WORD OF CAUTION

The article exhaustively lists all the innovations and refinements in technique from India. There are not many "true" major innovations or genuinely innovative techniques. With such a huge patient load and highly accomplished interventional pediatric cardiologists, we should have come up with not only more innovations but also fresh and novel ideas. A few may criticize the fact that some newly developed Indian devices are not genuine innovations but are inspired by established Western technologies. To have any significant impact, Indian innovations must be practice-changing or significantly reduce costs. We also need to create robust and ethical frameworks for collaboration with industry.

Enthusiasm for innovation should be matched with caution in patient selection. Ideally, case selection should involve

a heart-team approach that includes surgeons. This is especially true for conditions where surgery has been time tested, and the interventional alternative is still experimental. A good example is SV ASD in the young. The striking paucity of long-term follow-up is a critical shortcoming. Carefully collected long-term data from multiple centers through independent prospective registries is needed to determine the patient's benefit (or risk). Pediatric cardiology, in general, and especially interventions, lack evidence for their safety and efficacy.[94,95] Pediatric cardiac interventions are rarely compared to surgery in adequately powered randomized controlled trials. In India, structured regulatory approvals for new and innovative procedures are lacking or are in primitive stages.[5] This is possibly one reason why India remained a laboratory that aided many historical developments, including the first PTMC and percutaneous VSD closures.

Many young Indian pediatric cardiologists are forced to focus only on interventions, which may foster future innovations.[96] However, it often may result in undesired consequences. The unregulated, possibly unindicated, epidemic of device closure of small perimembranous VSD across India could be one case in point. We must keep the age-old words of Hippocrates in mind:

"*The physician must be able to tell the antecedents, know the present, and foretell the future – must mediate these things, and have two special objects in view with regard to disease, namely, to do good or to do no harm.*"

Often, it is challenging to apply "*primum non nocere*" (first, do no harm) in real-world decisions in pediatric cardiac interventions because estimates of risk and benefit are uncertain and are prone to error. This should remind us of the need for high-quality research to help us make informed decisions about the risks and benefits of the procedures we recommend. As intervention pediatric cardiologists, we should neither overestimate our capacity to heal nor underestimate our capacity to cause harm.

CONCLUSIONS

Despite an enormous burden of children with critical CHDs and a scarcity of specialty centers and pediatric cardiologists, India has made significant contributions to the science and practice of pediatric cardiac interventions.

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Conflicts of interest

There are no conflicts of interest.

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APPENDIX 1: INDIAN INNOVATIONS IN PEDIATRIC INTERVENTIONS: THE METHODOLOGY USED AND THE DISCLAIMER

METHODOLOGY

We used a multi-pronged approach to collate the information on innovations in pediatric cardiac interventions from India. An initial effort was made for a presentation during the 8th World Congress of Pediatric Cardiology and Cardiac Surgery held from August 27 to September 1, 2023, in Washington, DC, United States. A more refined search was made for writing the article.

Search the databases

We searched the electronic database of PubMed for the relevant studies originating from India (from inception to September 2024). The search terms included "congenital heart disease" OR "congenital heart defect," OR "pediatric cardiology" OR "pulmonary valve implantation" OR "atrial septal defect" OR "ventricular septal defect" OR "patent ductus arteriosus" OR "device closure" OR "RSOV" OR "coarctation" AND "India." We specifically looked for the earliest publication on a relevant question or publications reporting the largest device size or smallest patient size. We also manually searched the reference list of relevant articles. Any landmark or prominent pediatric cardiac intervention series was also selected.

Email

An email asking about their own or colleagues' innovations in pediatric cardiac interventions was sent to all the members of the Pediatric Cardiac Society of India.

Thought leaders

We reviewed the list of innovations with the leaders in the field. We tried connecting with the leading academicians from India to check for significant omissions and commissions. They also suggested a few innovations that were also included. We thank the following leaders in the field for their suggestions and contributions in making this article more comprehensive. Dr. Bharat Dalvi, Dr. J. M. Tharakan, Dr. Anita Saxena, Dr. Shyam S Kothari, Dr. Raghavan Subramanyan, Dr. R. Suresh Kumar, Dr. R. Krishna Kumar, Dr. Snehal Kulkarni, Dr. M. Jayranganath, Dr. K. Sivakumar, Dr. Edwin Francis, Dr. Saurabh K. Gupta, and Dr. Anand Subramanian, among others.

We followed specific rules:

1. The article must be published by September 2024 in an indexed journal
2. Most part or major work should have emanated from India
3. We do not wish to document who performed a routine procedure first in India. Such information was not collected.

DISCLAIMER

Despite our best efforts, we could have missed a few crucial innovations inadvertently for various reasons. However, we made the best effort to make the list as complete and accurate as possible. Such an effort may have some inaccuracies and errors of omission. We regret such inadvertent omissions and commissions.