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Research Letter

Transcatheter interventions in congenital heart diseases using reusable cardiovascular catheters and devices

Sir,

We read with interest the recently published consensus document by Amit Vora et al.[1] In the year 1997, the INDIAN SOCIETY OF CARDIOLGY brought its first consensus regarding the reuse of single used devices(SUDs). The current consensus provides a crystal clear image of reuse of single used device (SUDs) in cardiovascular intervention in our time and its future for the developing world and developed world. All around the world, the intervention cardiologists have been reusing SUDs since 1970s based on the consensus of individual institute.[2] The intervention cardiologists in developing world reuse the SUDs because of inadequate financial support while others reuse SUDs to reduce pollution,save money and the practice is found be safe.[3,4] Inadequate cleaning, deposits of sterilizing chemicals, cross infections, device failure and loss of functional integrity due to wear tear and medicolegal issues discourages such practice in some countries.[5] We shared our experience of percutaneous device closure of various congenital cardiac defects using a new occluder but sterilized supportive hardware like delivery sheath, delivery cable and device loader. The sterilization protocol follows the consensus of INDIAN SOCIETY OF CARDIOLOGY.[1,6] Maximum frequency of reuse of SUDs was 3 times. This retrospective observation was from January 2015 and December 2016. A total of 368 congenital cases were admitted for catheterization during study period with different issues. Out of them 96 cases were chosen for therapeutic interventions. Informed consent is obtained from all the patients after well informing that the procedure would be done using new devices (occluder and balloon) with or without FDA approval and sterilized supportive hardware because of limited fund support from Orissa state treatment fund(OSTF) or Aarogyasri Health Care Trust of Telangana state. Approximately ≥90% of the cardiac interventions were done in this study were finically supported by Orissa State Treatment Fund(OSTF) or Aarogyasri Health Care Trust of Telangana state. The provided fund was not enough for using FDA approved devices (occluder and coils) and obviously, there was nil financial support for the supportive hardware (sheaths, delivery cables, guide catheters, loaders, retrieval devices etc.). For example, procedure like PTMC were not at all possible under these schemes during study period. Therefore, a comparison study between using new devices with new supportive hardware vs sterilized hardware were not possible in this study. We had not come across any instance for denying consent for using sterilized supportive hardware. For device closure, we used CARDIO-O-FIX devices of Stairway Medical Technology. Gianturco coils (Cook Cardiology, Inc., Bloomington, Indiana), used for coil closure of small PDA of size less than 2.5 mm. ATLAS balloon of BARD Company were used for balloon valvuloplasty. In almost all the cases, we used new devices but supportive materials like sheaths, catheters, pressure lines, delivery cables and devices loaders etc. were chemical, moist heat and ETO sterilized as per guidelines and consensus.[5,6] Once the procedure has been done, a strict follow up to 1month was done. The age of patients who underwent therapeutic intervention ranged from 21 days to 67 years with median age of 14 years. Out of 96 patients, females were 56(58. 3%).Seventy six percent of had hemodynamically significant lesions. Out of 96 interventions, PDA: 37(38.5%), ASD: 32(33.3%), isolated valvular pulmonary stenosis: 14(14.6%), bicuspid aortic valve disease: 8(8.3%), Shone complex (for Coarctation of aorta):2, VSD:1, coronary cameral fistula:1 and hypoplastic left heart syndrome (HLHS) (for ductal stenting):1. The intervention was successful in 89(92.7%) of cases. We failed in 3 cases of ASD, 2 cases of PDA, 1 each of VSD, HLHS (PDA ductal stenting) and isolated pulmonary valvular stenosis. In 2 cases of ASD intervention, we faced difficulty in negotiating device ETO sterilized sheaths which was improved by upgrading sheath size. During the immediate follow up of the procedure (before discharge) 2 patients had complications, one case of PBAV had moderate aortic regurgitation on echo, and 1 patient of ASD device closure had CVA but those were not issues related to the reuse of sterilized supportive hardware like delivery sheath, delivery cable and loaders etc. A comparative study using new device and new supportive hardware vs new device and sterilized hardware would have provided a better picture. There were 2(2.08%) deaths in the immediate follow up period (before discharge), of them 1 patient was attempted for PDA ductal stenting and the other had undergone PBAV. The follow up of patients post discharge is 1 month without any complications not particularly related reuse of SUDs. There were no evidences of infective endocarditis.

The financial support for catheter based intervention from Odisha state treatment fund (OSTF) or Aarogyasri Health Care Trust is inadequate which are the affiliating institutes linked to this study.[7,8] The cost of only a new occluder (not FDA approved) for atrial septal defect, patent ductus arteriosus and ventricular defect was approximately sixty thousand and the cost of FDA approved devices like Amplatzer devices were still higher. The procedural charge was kept only five to six thousand using sterilized supportive hardware. The financial support provided by various government schemes is only six thousand. Therefore, with the limited financial support from government, it was not even possible to perform device(new) closure using sterilized supportive hardware. When everything is taken new including the cost of each device closure crosses 150,000 rupees. This higher cost was afforded by less than 10% of patients. The hardware used in these cases were properly sterilized using the consensus by ISC,1997 and

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2017.[1,6] for other patients after sterilizing. Because of lack of adequate financial support, some procedure like percutaneous mitral valvotomy was not possible during study period for the patients for whom Aarogyasri or OSTF was funding. In the other hand, to reduce pollution, adherence to the rule of "three R" (reduce, recycle and reuse) is required for sustainable development.[9] The safety of reuse of devices, catheters and sheaths used in different cardiovascular intervention is proved in several studies.[5]

The current consensus on reuse of devices in cardiovascular would decisively help cardiovascular practicenor from either world i.e. the one from limited resources by recycling and reusing SUDs and the other who practice in affluence countries by reducing pollution. Even though we had the constraint of equipment and finance, our study highlights the successful and safety recycling of devices and accessories used in cardiovascular intervention in congenital heart diseases.

Conflict if interest

None.

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Ramachandra Barik*
PavanKumar
All India Institute of Medical Sciences, Bhubaneswar 751019, Odisha, India

Nizam's Institute of Medical Sciences, Hyderabad 500082, Andhra Pradesh, India

* Corresponding author.
E-mail address: cardioramachandra@gmail.com (R. Barik).

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