INCIDENCE, MANAGEMENT AND SUBSEQUENT OUTCOME OF TRANSCATHETER EMBOLIZED DEVICES- THREE YEARS AUDIT AT A TERTIARY CARDIAC CARE CENTER

Khurram Akhtar, Maad Ullah, Nadeem Sadiq, Mehbood Sultan, Hajra Akbar

Armed Forces Institute of Cardiology & National Institute of Heart Diseases, Rawalpindi

ABSTRACT

Objective: To audit the incidence of misplaced devices during varied interventional procedures carried out in our catheter lab over a period of three years.

Study Design: Descriptive study

Place and Duration of Study: Armed Forces Institute of Cardiology & National Institute of Heart Diseases. From January 2011 to December 2103

***Material and Methods*:** All adult and pediatric cases with structural heart disease both congenital and acquired undergoing interventional procedures were included in the study. Out of a total of 3256 patients, 1174 patients who underwent cardiac catheter device implantation procedures during the study period were included in the study.

Results: Nineteen patients out of 1174 patients (1.6%) had device embolization acutely or sub acutely following the procedure. The varied reasons for the device embolizations were analyzed in this study.

Conclusion: We concluded that for retrieval to be successful via the transcathter approach, it was important to have a wide selection of retrieval equipment available and to be conversant with its use. Our audit also concludes that device implantation at our center are safe and an effective procedure with minimal complications.

Keywords: Transcatheter embolized devices, Interventional procedures.

INTRODUCTION

In this retrospective analysis we aimed to audit the incidence of misplaced devices during varied interventional procedures carried out in our catheter lab over a period of three years. The analysis helped us understand our inadequacies and gave us an improved insight on our competence level when we compared a similar number of cases carried out internationally. Needless to say, the analysis helped improve our standards of patient care, important both from the patient and physician's point of view. The analysis under consideration however has been recurrently deliberated before in the international journals. This brief study only aimed to add a little more weight in the currently available data published elsewhere.

Present study was carried out to assess the incidence and subsequent management of misplaced devices as a complication of therapeutic percutaneous transcatheter device procedures in both children and adult patient population being treated at a tertiary care unit over a 3 year period at Rawalpindi. Our analysis was restricted to the 1174 cases of therapeutic variety with device implantations only.

MATERIAL AND METHODS

The descriptive study was carried out in a tertiary cardiac unit of Pakistan. The data under consideration spanned over a period of three years from January 2011 to December 2103. All adult and pediatric cases with structural heart disease both congenital and acquired undergoing interventional

Correspondence: Dr Khurram Akhtar, AFIC/HIHD Rawalpindi.
Email:
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procedures were included in the study. Patients with coronary artery disease were not included in the study. Since the study was a retrospective analysis of catheter-based procedures already accomplished, no informed consent was necessary. A total of 3256 patients underwent cardiac catheter procedures; out of which 1476 patients (44%) underwent therapeutic cardiac catheter procedures. Therapeutic procedures could be broadly categorized as dilations valvuloplasty, angioplasty, and endovascular stenting or as closures (vascular embolizations and device closure of defects). Our sample size-1174 patients (36%), included those patients who underwent device implantations during the varied therapeutic procedures. Patients were included in the study through non-probability convenience sampling. Data analysis was done using SPSS version 11. Mean and standard deviation (SD) were calculated for quantitative variables. Frequency and percentages were calculated for qualitative variables.

RESULTS

Our analysis was restricted to the 1174 cases of therapeutic variety with device implantations only. Median age of the patients undergoing interventional procedure was 6 years. Forty six percent of the patients were males. These procedures included device implantations in isolated atrial septal defects (ASD) secundums, and patent ductus arterosis (PDAs), ASD secundums with PDAs, ASD secundums with pulmonary stenosis, ASD secundums with aortic stenosis, ASD secundums with mitral stenosis, PDA with Pulmonary stenosis, PDA with aortic stenosis, isolated VSDs, ischemic VSRs, duct dependent cardiac lesions requiring ductal stent implantations, PDA coilings, multiple aorta pulmonary collateral arteries (MAPCAS) coiling's, device closures of surgically placed shunts and PDA device occlusion of coronary atrio ventricular (AV) fistulas. Nineteen patients (1.6%) had device embolization acutely or sub acutely following the procedure. Of the 19 patients, 12 (63%) cases were females. Age range of patients with embolized devices was 9months to 22 years. Amongst the ASD, the size of the defect ranged from 4mm to 40mm with a mean size of 19 mm and a mode of 12mm. Amongst the ASD occluder's device size ranged from 5mm to 46 mm. Maximum number of cases implanted with ASD occluders were in the defect size range of 10 mm to 22 mm and in the defect size range of 24 mm to 30 mm. Six ASD devices embolized in our series. Number of ASD devices that could be snared and redeployed werethree. Amongst the PDA occluders, the size of the ductus ranged from 2 mm to 16 mm with a mean duct size of 4.67 mm and a modal value of 2 mm. A variety of device sizes were used. Amongst the PDA occluders, the device size ranged from 3.5/5 mm to 18/16 mm with the maximum number of PDA occlusions using device size 8/6, followed by size 10/8 and 6/4 in that descending order respectively. Complications included, device embolizations leading to percutaneous or surgical retrievals, weak femoral pulses, major vessel damage leading to femoral arteriotomy. Of the seven PDA devices that embolized in our series, we were successfully able to retrieve only two PDA devices. We had four embolized VSD devices but unfortunately none could be retrieved via the transcatheter route. There was one case of bare metal stent embolization into the main PA. The patient however could not survive

the cathter procedure. Thus in a total of 19 cases, in only 5 (26%) cases we were able to retrieve the device with the help of catheter and snare wire successfully. In 14 (74%) cases we were unable to retrieve the device in the catheter laboratory despite our efforts and had to resort to surgical removal.

We also experienced that catheter removal of an ASD occluder was technically much easier than the removal of an embolized PDA occluder. The reason could be the prominent screw sleeve welded to the right atrial disc of the Amplatzer ASD occluder. Surgical help was sought early in most cases, immediately after the catheterization procedure and no later than 24–48 hour, and during the same hospitalization. Only in two cases was the surgical retrieval carried out as a planned procedure. In our series, there were two (10.5%) deaths, rather indirectly from congestive cardiac failure (CHF) and from severe desaturation. No death was recorded resulting directly as a consequence of device embolization. Of the two deaths, one 22-year-old mother, had an unsuccessful VSD device closure. The patient had lower segment cesarean section (LSCS) 24 hours earlier and was shifted on ventilator from ITC with worsening CHF. She died as a result of CHF and generally poor condition. In another patient we were unable to deploy a PDA stent into the ductus and consequently the patient died because of continued worsening desaturation.

We calculate our embolization rate to be 1.6%, which is well within the acceptable international standards. Our audit concludes that device implantation at our center are safe and an effective procedure with minimal complications.

DISCUSSION

Congenital heart disease (CHD) constitutes 6-12/1000 live births[1]. Over the past decade, transcatheter interventions have become increasingly important in the treatment of patients with CHD. Although closure of left to right shunting defects by percutaneous occluder devices has a lot of advantages, device embolization is still a major complication[2,]. In fact, it has been shown that the number of congenital defects closed by means of catheter-delivered devices has risen dramatically, raising the question of whether the introduction of percutaneous closure may be driving use[2,3]. If embolized device retrieval fails with percutaneous intervention attempts, surgical management is the only method to remove embolized devices[2-5,10]. Percutaneous transcathter device occlusion of vessels and septal occluders achieve the same desired results as surgical procedures[13]. The percutaneous approach is safe, incurs less morbidity, a short hospital stay and is cosmetically acceptable[5]. However, the procedures are attendant with certain complications; most common of which is device embolization, vessel damage, thromboembolism, air embolism, heart perforation, mitral and aortic valve damage, endocarditis, stroke, tamponade and arrhythmias[15,16,17]. The scope of this audit was however limited to the most frequent complication of device occluders, i.e. is embolization. Our analysis suggested that we were able to successfully implant devices in almost 98% of the cases. In 1.6% of the cases we had to face device embolization. The reasons cited for the complications could be ascribed to wrong choice of the device (which includes device size and shape), inadequate rim margins of the defect[16], excessive muscle

movement in case of VSD occluders[19, 20], lack of clear morphology of the defect, learning curve of the operator, small patient size with attendant difficulty in correct device deployment.

CONCLUSION

Device closure is a safe and effective method with acceptable complication rates. However, learning curve, right sizing, extra care and caution, ensures effective device placement. Misplacement of a device during therapeutic embolization is a recognized complication that can be satisfactorily dealt with by transcatheter retrieval without recourse to surgery or removed surgically. However for retrieval to be successful it is important to have a wide selection of retrieval equipment available and to be conversant with its use.

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