

Trends in the number of cardiac surgical procedures after the introduction of routine catheter intervention for isolated congenital shunt lesions

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Abstract

Background and Aims: The study aimed to evaluate the trends in the number of cardiac surgeries after the introduction of routine catheter intervention for isolated shunt lesions.

Methods: A retrospective observational study was conducted which studied the trends in the total number of cardiac surgeries from 2012 to 2019 with the introduction of catheter interventions for isolated shunt lesions for the same period in Shahid Gangalal National Heart Center, Kathmandu, Nepal. The change in the total number of surgeries and surgeries for isolated shunt lesions after the start of the catheter intervention was evaluated. The pre-catheter intervention era and catheter intervention era spanned from 2012 to 2015 and 2016 to 2019 respectively.

Results: During the catheter intervention era, out of total 2590 isolated shunt lesions, 1300 were closed by catheter intervention procedure (50%). Only 44%, 11%, and 90 % of Atrial Septal Defect, Patent Ductus Arteriosus and Ventricular Septal Defect respectively were closed surgically. Interestingly, even after introduction of catheter intervention, both the total number of surgeries and surgeries for congenital heart disease (CHD) did not decrease and remained above 1200 and 500 cases per annum respectively. The expected increment in the surgical number for most of the years was achieved following the country's population growth remained at 1.8%, even though a large portion of isolated shunt lesions were closed by catheter intervention procedure.

Conclusion: Though a significant number of isolated shunt lesions were closed by catheter intervention procedure, the number of surgical procedures for congenital as well as total cardiac surgeries did not decrease in number.

Keywords: Trends in Cardiac Surgeries, Catheter Intervention, Isolated Shunt Lesions

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Introduction

Isolated shunt lesion: atrial septal defect (ASD), ventricular septal defect (VSD) and patent ductus arteriosus (PDA) can be closed either surgically or through the catheter intervention. Surgery has been the mainstay of treatment for these structural congenital heart defects in children and adults for over half a century. Interventional catheter procedures have emerged as an alternative to surgery for some lesions over the last 20 years.¹ With the advance in technology along with increased availability and refinement of indications, catheter interventions have become the procedure of choice in many centers for the treatment of isolated shunt lesions whenever it is anatomically suitable. Catheter intervention has the potential for anatomical correction along with reduced early morbidity.²

Shahid Gangalal National Heart Center, a tertiary level cardiac center in Nepal is doing surgical repair of these lesions since the start of the operative services. At the center, the first case of patent ductus

arteriosus ligation was done on 23 August 2001.³ The first cardiac surgery under cardiopulmonary bypass was ASD closure and was done on 3rd September 2001.³ The catheter intervention for shunt lesion was introduced in 2006 but initially only around 25 catheter interventions were performed annually. Since 2016, number of catheter interventions increased rapidly and the number have reached around 200 cases per year since then. For the study purpose, the period is divided into pre-catheter intervention era (i.e., from 2012 to 2015) and post-catheter intervention era (i.e., from 2016 to 2019). The number of surgical procedures is in increasing trend each year since the start of the services at the center. We do not know about the impact on the number of surgical procedures with the introduction of catheter procedures. This study is designed to evaluate the trends in both the number of surgeries for CHD and in the total number of surgeries with the introduction of the routine catheter intervention for isolated congenital shunt lesion at the center.

Methods

The total cases of surgical procedures, the total cases of surgical procedures for CHD, and the total cases of surgical procedures for isolated shunt lesions per year from 2012 to 2019 were studied from hospital records. Similarly, the total cases of catheter interventions for isolated shunt lesions per year from 2016 to 2019 were also studied. The study included in the total number of CHD surgeries were both the on-pump and off-pump surgeries for congenital heart diseases. The total number of surgeries included the above-mentioned surgeries for CHD in addition to surgeries for coronary artery bypass surgery, valve surgery, surgery for cardiac mass, pericardiectomy for chronic constrictive pericarditis. Excluded in the study were surgeries for vascular rings, immediate revision surgeries, re-exploration for mediastinal bleeding, sternum wound infection, diaphragmatic palsy, thoracic duct ligation, re-exploration for excessive bleeding, surgical site infection, arterio-venous fistulas, femoral artery embolectomy, peripheral artery bypass surgeries, and isolated carotid endarterectomy.

In catheter intervention procedure (CIP) isolated shunt lesion (ISL) like ASD, PDA and VSD were included. When patients had more than one CHD, the most severe defect was chosen according to a hierarchy published previously.^{4,5} The collection of data was started after the approval of the study by the institutional review committee of the study center. The periods from 2012 to 2015 and from 2016 to 2019 were considered the pre-catheter intervention era and the catheter intervention era respectively. Number of Surgeries from 2012 to 2019 and the expected number calculated based on current population growth of Nepal 1.8%.⁶ The yearly rate of increment in the total number of operations was calculated and compared the rate of increment between pre-catheter and post-catheter intervention eras. Also, a record has been made of the change in the number of surgical procedures for isolated shunt lesions between the pre-catheter and post-catheter interventions era. An evaluation has been done to evaluate ratio of catheter interventions for isolated shunt lesion out of the total number of procedures for isolated shunt lesion each year during the catheter intervention era.

Statistical methods: The data were collected and uploaded in Excel (Microsoft) and transferred to IBM statistical program for social sciences (SPSS) version 20.0 for statistical analysis. The categorical data were expressed as counts and percentages. Fisher’s exact test was used to compare the categorical variables.

Results

The total number of surgical procedures performed from 2012 to 2019 was 10453. The catheter intervention for ISL was performed on a total of 1300 cases during catheter intervention era i.e., from 2016 to 2019. The total number of cardiac surgical procedure and CIP for ISL performed each year between 2012 and 2019 are presented in table 1.

Table 1: Yearly distribution of total number of surgeries and device closure for atrial septal defect (ASD), patent ductus arteriosus (PDA), ventricular septal defect (VSD) along with total congenital heart disease (CHD) surgeries and total number of surgeries.

| Year | ASD | | PDA | | VSD | | Number of CHD surgeries | Total number of surgeries |
|------|---------------------------|-----------------------------|---------------------------|-----------------------------|--------------------------|----------------------------|-------------------------|---------------------------|
| | Number of Device closures | Number of surgical closures | Number of device closures | Number of surgical closures | Number of device closure | Number of surgical Closure | | |
| 2012 | 19 | 219 | 6 | 82 | 0 | 110 | 470 | 1011 |
| 2013 | 24 | 239 | 16 | 68 | 0 | 113 | 533 | 1174 |
| 2014 | 28 | 198 | 4 | 69 | 0 | 107 | 450 | 1160 |
| 2015 | 28 | 210 | 5 | 74 | 0 | 96 | 447 | 1117 |

| | | | | | | | | |
|------|-----|-----|-----|----|----|-----|-----|------|
| 2016 | 123 | 248 | 43 | 36 | 1 | 118 | 529 | 1259 |
| 2017 | 160 | 185 | 109 | 8 | 14 | 137 | 541 | 1568 |
| 2018 | 251 | 191 | 153 | 6 | 36 | 123 | 516 | 1652 |
| 2019 | 258 | 194 | 127 | 3 | 25 | 111 | 518 | 1512 |

Figure 1: Trends in the management of Atrial Septal Defect (ASD), Patent ductus arteriosus (PDA) and Ventricular septal defect (VSD)

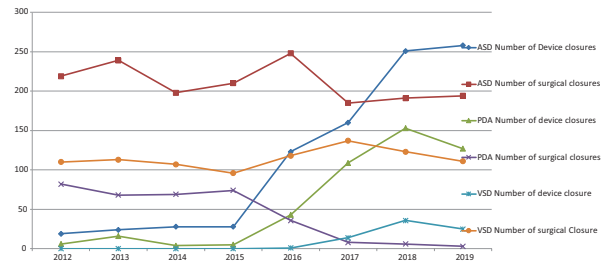
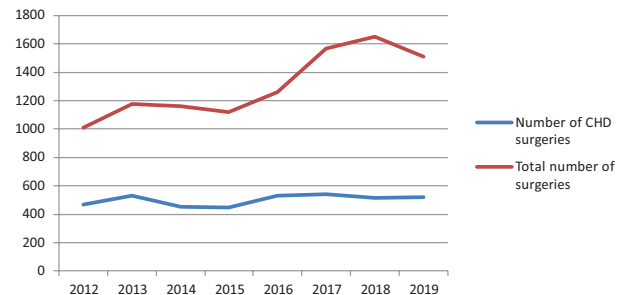


Figure 2: Trends of total number of surgery and number of surgeries for congenital heart disease (CHD)



During the catheter intervention era the number of surgeries for CHD remained static above 500 and total number of surgeries remains above 1200 (Fig no 2).

Considering the population growth of Nepal at 1.8 % per year, the expected increment in the number of surgeries each year was achieved. This is presented in table number 2. The increment in the number of surgeries corresponding to national population growth rate is basic to denote that there is no decrease in the number of surgeries even though a large portion of isolated shunt lesions were done by interventional cardiologist through CIP.

Table 2: Number of Surgeries from 2012 to 2019 and the expected number based on Population Growth

| Year | Total Number of Surgeries | Expected Surgeries Based on Population Growth Rate of 1.8% |
|-----------------------------|---------------------------|------------------------------------------------------------|
| Jan 1, 2012 to Dec 31, 2012 | 1011 | 1011 |
| Jan 1, 2013 to Dec 31, 2013 | 1174 | 1029 |
| Jan 1, 2014 to Dec 31, 2014 | 1160 | 1195 |
| Jan 1, 2015 to Dec 31, 2015 | 1117 | 1181 |

| | | |
|-----------------------------|---------|---------|
| Jan 1, 2016 to Dec 31, 2016 | 1259 | 1137 |
| Jan 1, 2017 to Dec 31, 2017 | 1568 | 1282 |
| Jan 1, 2018 to Dec 31, 2018 | 1652 | 1596 |
| Jan 1, 2019 to Dec 31, 2019 | 1512 | 1682 |
| Mean | 1306.63 | 1264.12 |
| SE | 83.93 | 87.84 |
| t-score | 0.35 | |
| p-value | 0.7316 | |

Table 3: Ratio of Isolated Shunt Lesion out of total surgeries and total surgeries for congenital heart disease (CHD)

| | Before catheter era 2012-2015 | During catheter era 2016-2019 | t-score | p value |
|--------------------------------------------------------|-------------------------------|-------------------------------|---------|---------|
| Total number of surgeries | 4462 | 5991 | | |
| Total number of surgeries for CHD | 1900 | 2104 | | |
| Total number of surgeries for isolated shunt lesion | 1585 | 1360 | | |
| Percentage of ASD surgery out of total CHD surgery | 45.58% | 38.88% | 4.29 | <0.001 |
| Percentage of PDA surgery out of total CHD surgery | 15.42% | 2.52% | 14.40 | <0.001 |
| Percentage of VSD surgery out of total CHD surgery | 22.42% | 23.24% | 0.62 | 0.2684 |
| Percentage of ASD surgery out of total cardiac surgery | 19.41% | 13.71% | 4.84 | <0.001 |
| Percentage of PDA surgery out of total cardiac surgery | 6.57% | 0.88% | 9.41 | <0.001 |
| Percentage of VSD surgery out of total cardiac surgery | 9.55% | 8.16% | 1.54 | 0.0620 |
| Ratio of CHD out of total Surgery | 42.58% | 34.72% | 5.11 | <0.001 |

| | | | | |
|-------------------------------------------------------------|--------|--------|-------|--------|
| Ratio of isolated shunt lesion out of total cardiac surgery | 35.52% | 22.70% | 8.98 | <0.001 |
| Ratio of isolated shunt lesion out of total CHD surgery | 83.4% | 64.6% | 13.95 | <0.001 |

Though there is a significant decrease in the portion of ASD and PDA surgery (table no 3), there is no decrease in total numbers of both surgeries and total numbers of surgeries for CHD during the catheter era (figure no 2). Whereas, there is no significant decrease in the number of VSD surgery during the catheter era (fig no 1 & 2).

Table 4: Yearly Percentage of Device Closure for Individual Shunt Lesion out of Total Procedure for the Corresponding Isolated Shunt Lesion

| Device closure for isolated shunt lesion | Year | | | |
|----------------------------------------------|------|------|------|------|
| | 2016 | 2017 | 2018 | 2019 |
| Device closure for atrial septal defect | 33% | 46% | 73% | 73% |
| Device closure for Patent Ductus Arteriosus | 54% | 93% | 96% | 97% |
| Device closure for Ventricular Septal Defect | 0.4% | 9% | 22% | 18% |

The portion of ASD device closure was doubled between 2018 and 2019 compared to that between 2016 and 2017. More than 90% of PDA was closed by CIP in 2017, 2018 and 2019. Percentage for VSD device closure ranged from 0.4 % to 22% during the catheter era. Surgical VSD closure is still popular compared CIP for VSD closure. This shows a significant portion of ASD and PDA is closed by CIP whereas VSD is still popular with surgical closure. This will be the trend of management of ISL in the present era.

Discussion

Sufficient work load in cardiac surgery for job satisfaction is an important attraction factor towards this super-specialty for beginners. This study is designed to evaluate change in the work load of cardiac surgeon with the introduction of routine catheter intervention procedure performed by interventional cardiologist for isolated shunt lesion at a tertiary level cardiac center of Nepal. This study analyzed the trend in surgical and catheter intervention for the management of isolated shunt lesion. The lack of similar studies in sufficient number makes direct comparison difficult. There are studies from England and Denmark which are a bit similar to our study design and so give us an idea to compare our results. What we found was a significant rise in catheter intervention but without any discernible impact on the number of surgical procedures. The popularity and feasibility of ASD and PDA for device closure had significantly changed the trend in their surgical number. Whereas, the number of VSD device closure was not able to bring a significant change in the trend of surgery for VSD. However, with the invention of newer device and technique for VSD closure in future may change the trend of VSD closure. ASD, PDA and simple VSD are considered simple cardiac surgeries which are always done by beginner surgeons in this field. When these are closed with CIP by interventional cardiologist learning phase for newer surgeon will be prolonged. Trends in CIP and surgical closure for the treatment of isolated congenital shunt lesions plot the advancement in cardiac field over the last decade Overall cardiac surgeons need not to worry about the volume of their work load due to the introduction of newer

technology for cardiac intervention. Development of science in the cardiology field is good for human kind. The most important benefit is that with the introduction of regular CIP for isolated shunt lesion, the surgeon got opportunity to concentrate on complex cases.

Though a large number of ASD and PDA was closed by catheter-based intervention, the number of surgeries for CHD and the total number of surgeries have not decreased, and this finding is similar to that of the publications from England and The Netherlands^{1,2}.

ASD: Ostium secundum atrial septal defects (ASD) are one of the most common forms of congenital heart diseases with an incidence of 6 to 10 per 10,000 live births.⁷ This type of defect accounts for nearly 75–80% of ASD cases. This is the only type of ASD that is potentially amenable to percutaneous device closure.⁸ Transcatheter closure of secundum ASD is being increasingly used as the primary intervention in recent years. Although randomized comparisons with surgery are lacking comparative trails have demonstrated less morbidity after transcatheter closure.⁹ The first TC-ASD closure, at the center, was done in 2006. The surgical closure is indicated primarily when rim of septal tissue is < 5mm and therefore inadequate for device placement.^{10,11} The ongoing concerns relate to device design and potential for cardiac erosion, reported between 0.1 and 0.3% with a reported mortality rate of 7%.¹¹ The causes of erosion are unclear; however, associations with larger, oversized devices with deficient rims have been documented.¹²

In the study, during catheter era device closure of ASD is reported at 43%, 46%, 73% and 73% of all ASD procedures in 2016, 2017, 2018 and 2019 respectively. According to a Danish study published by Larsen et al. (2017) reported the TC-ASD closure at 48.2%.¹³ In the last two years of the study period, ASD was predominantly closed by transcatheter technique i.e., >70%. Similar finding was made in the USA as well. More than 80% of isolated ASD treated at primary pediatric hospitals were closed in the catheterization laboratory.¹⁴

Even though a large portion of ASD was closed with a device, there was no decrease in the number of CHD surgery which remained static around 500 and the total number of surgeries stood around 1500 in the last three years of study period. A similar trend was observed by Farooqi M. et al.¹

PDA: In this study, more than 90% of PDA was closed with CIP during the last three years of catheter intervention era. This stands closer to a Danish study where they had closed 95% of PDA with CIP, PDA was the most popular among all isolated lesion for device closure.¹³ Though, this had changed the trend in the management for PDA, there was no decrease in the number of surgeries for CHD and the total amount of surgery.

VSD: The surgical closure is a standard for patient with VSD. Device closure is considered as an alternate to surgery in pediatric and adult patients with a muscular VSD with an adequate rim of septal myocardium.^{9,10} Our portion of CIP for device closure of VSD out of the total procedure for VSD was at 10%, which is more than that of the Danish study at 2.4%.¹³ This difference may be because of the difference in the distribution of the type of VSD among European and Asian populations. Despite advancement in catheter technology, device migration and delayed heart block that occur late after implantation in 5 % of perimembranous VSD may be the cause of risk of sudden death.¹⁵

Limitation

This was a retrospective study done in a single cardiac center. There was always a risk of misclassification of diagnoses and procedures as data were collected from hospital records. The evaluation of the effect on the total number of surgeries and total number of CHD surgeries were made only relative to catheter intervention for ISL. The effect on surgical number was not evaluated due to aggressive percutaneous coronary intervention, transcatheter valvotomy and PDA stenting. We need to re-evaluate this trend

with expected momentum of newly started transcatheter valve replacement service at the center. With the possible implementation of a research phase, percutaneous cavo-pulmonary shunt, center shunt, newer devices for VSD and the trends in the number of CHD should also be considered in future. We did not evaluate the age of the patient in each procedure. The conclusion made here may not be applicable to other centers.

Conclusion

Catheter device closure has become the procedure of choice for ASD, PDA but the marked increase in the procedures has not reduced over all surgical workload. On the other hand, it has had minimal impact on the management of VSD.

Conflict of Interest None

Source of fund None

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