Comparison of cost-effectiveness and postoperative outcome of device closure and open surgery closure techniques for treatment of patent ductus arteriosus

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Original Article

Abstract

BACKGROUND: Various devices have been recently employed for percutaneous closure of the patent ductus arteriosus (PDA). Although the high effectiveness of device closure techniques has been clearly determined, a few studies have focused on the cost-effectiveness and also postoperative complications of these procedures in comparison with open surgery. The present study aimed to evaluate the clinical outcome and cost-effectiveness of PDA occlusion by Amplatzer and coil device in comparisong with open surgery.

METHODS: In this cross-sectional study, a randomized sample of 201 patients aged 1 month to 16 years (105 patients with device closure and 96 patients with surgical closure) was selected. The ratio of total pulmonary blood flow to total systemic blood flow, the Qp/Qs ratio, was measured using a pulmonary artery catheter. The cost analysis included direct medical care costs associated with device implantation and open surgery, as well as professional fees. All costs were calculated in Iranian Rials and then converted to US dollars.

RESULTS: There was no statistical difference in mean Qp/Qs ratio before the procedure between the device closure group and the open surgery group (2.1 ± 0.7 versus 1.7 ± 0.6, P = 0.090). The mean measured costs were overall higher in the device closure group than in open closure group (948.87 ± 548.76 US$ versus 743.70 ± 696.91 US$, P < 0.001). This difference remained significant after adjustment for age and gender (Standardized Beta = 0.160, P = 0.031). PDA closure with the Amplatzer ductal occluder (1053.05 ± 525.73 US$) or with Nit-Occlud coils (PFM) (912.73 ± 565.94 US$, P < 0.001) was more expensive than that via open surgery. However, the Cook detachable spring coils device closure (605.65 ± 194.62 US$, P = 0.650) had a non-significant cost difference with open surgery. No event was observed in the device closure group regarding in-hospital mortality or morbidity; however, in another group, 2 in-hospital deaths occurred, two patients experienced pneumonia and seizure, and one suffered electrolyte abnormalities including hyponatremia and hypocalcemia.

CONCLUSION: Although open surgery seems to be less expensive than device closure technique, because of lower mortality and morbidity, the latter group is more preferable.

Keywords: Cost-effectiveness, Outcome, Device Closure, Open Surgery Closure, Patent Ductus Arteriosus

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Introduction

Within the past decade, various devices have been employed for percutaneous closure of the patent ductus arteriosus (PDA). Coil implantation, especially detectable release coils, are currently utilized particularly in small-diameter ducts.[1] However, in larger ducts, the use of this technique may be accompanied with procedural complexity,

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such as applying multiple coils.[2] In this regard, the Amplatzer duct occluder has been recently introduced as a device that is more appropriate for larger sized ducts and also has a high rate of success and safety for occlusion of PDA by the percutaneous approach.[3] Furthermore, this procedure results in high occlusion rate and a low rate of procedure-related complications.[4] Some recent studies have shown an occlusion rate higher than 99% during 6 months of device deployment.[5] Even, the majority of occlusions may have occurred within a day of device implantation. Moreover, although open surgical treatment of the PDA is a low-risk procedure, because of the necessity for general anesthesia, occurrence of surgery-related complications, and longer hospital stay, developing a catheter-based technique such as Amplatzer duct occlude and implantation of coils by this technique has gained more interest recently.[6,7] In this regard, although the high effectiveness of this technique has been clearly determined, few studies have focused on the cost-effectiveness and postoperative complications of this procedure in comparison with common applied treatment methods such as open surgery. The present study aimed to evaluate the clinical outcome and cost-effectiveness of PDA occlusion by Amplatzer and coil device in comparison with open surgery.

Materials and Methods

In this cross-sectional study, a randomized sample of 201 patients aged 1 month to 16 years (105 patients with device closure and 96 patients with surgical closure) were selected. The devices implanted for these patients included the Amplatzer ductal occluder (ADO) in 36 patients, Nit-Occlud coils (PFM AG, Köln, Germany) in 63 patients, and Cook detachable spring coils (CDC) in 6 patients. Clinical data, including gender and age, were collected from hospital-recorded files. Before assessment of the procedural results of operation, the ratio of total pulmonary blood flow to total systemic blood flow, the Qp/Qs ratio, was measured. In cardiac catheterization, using pulmonary artery catheter (a Qp/Qs ratio of 1:1) indicates that there is no shunting. A Qp/Qs ratio of > 1:1 indicates that pulmonary flow exceeds systemic flow and defines a net left-to-right shunt. Similarly, a Qp/Qs ratio of < 1:1 indicates a net right-to-left shunt. If the left-to-right shunt equals the right-to-left shunt in magnitude, it is possible to have Qp/Qs of exactly 1:1.[8]

Our cost analysis included direct medical care costs associated with device implantation and open surgery as well as professional fees. All costs were calculated in Iranian Rials and then converted to US dollars ($1 = 12260 Iranian Rials), and updated to 2013 dollars by using the grossdomestic product deflator. Our study endpoint was to evaluate and compare clinical consequences as well as cost-effectiveness of implanted device and open surgery. Results were reported as mean ± standard deviation (SD) for quantitative variables and percentages for categorical variables. The groups were compared using t-test or Mann-Whitney test for continuous variables and the chi-square test or Fisher's exact test if required for categorical variables. The multivariate linear regression analysis was used to assess between-group differences in analyzed direct costs with the presence of the two variables of gender and age. P values of 0.05 or less were considered statistically significant. All statistical analyses were performed using SPSS for Windows (version 19.0; SPSS Inc., Chicago, IL, USA).

Results

The average age of the study population was 4.37 ± 3.11 years (median 3.9 years) with female to male ratio of 1.9. No significant difference was revealed between the group with device closure and the group with surgical closure in mean age (4.20 ± 3.35 years versus 4.55 ± 2.83 years, P = 0.414) and the prevalence of female patients (66.7% versus 64.6%, P = 0.756). The mean Qp/Qs ratio was not statistically different between the device closure group and the open surgery group (2.1 ± 0.7 versus 1.7 ± 0.6, P = 0.090). The mean measured costs were overall higher in the device closure group than in the open closure group (948.87 ± 548.76 US$ versus 743.70 ± 696.91 US$, P < 0.001). In this context, PDA closure with the ADO (1053.05 ± 525.73 US$) or with PFM (912.73 ± 565.94 US$, P < 0.001) was more expensive than that via open surgery, but PDA closure with Cook coil (605.65 ± 194.62 US$, P = 0.650) had a non-significant cost difference with open surgery. The difference in direct cost between PDA closure by device implantation and open surgery remained significant after adjustment for age and gender (standardized beta = 0.160, t = 2.174, P = 0.031). Regarding postoperative complications, such as in-hospital mortality or morbidity, no events were observed in the device closure group. However, in the other group, 2 in-hospital deaths occurred (mortality rate of 2.1%), 2 patients experienced pneumonia and seizure, and 1 suffered

electrolyte abnormalities, including hyponatremia and hypocalcemia.

Discussion

The ADO and other device-based closure techniques have achieved a definite place in the armamentarium of the interventional cardiologist for the closure of partially large sized PDAs with an occlusion rate higher than 99% within a mid-term following operation.[9] Along with ADO, the PFM, including the detachable release coil, has proven to be an efficacious method for repairing PDA. By developing these nonsurgical closure procedures for treatment of the PDA, the incidence of residual shunt was gradually reduced, the complexity of treatment was considerably decreased, and the unsuitability of surgery for larger PDAs was resolved.[10-12]

The present study reported our recent experience on the use of different devise closure techniques for minimizing limitations of open surgery with regard to postoperative complications and its cost-effectiveness. Our observation could not support higher cost-effectiveness of these device-based techniques compared with open surgery; however, postoperative adverse events, including early mortality and morbidity, have been shown to be notably lower following employment of the former techniques. Thus, applying device-based closure techniques may be preferable in comparison with open surgeries. The main reason for occurrence of early complications after open surgery may be thoracotomy, and therefore trans-catheter methods were evolved to avoid thoracotomy.[13] The rare, but serious, complication of trans-catheter closure of the PDA is device embolization, which is relatively common early in the experience with coils. Followed by this complication, flow disturbance in the proximal left pulmonary artery or descending aorta from a protruding device, hemolysis from high-velocity residual shunting, femoral artery or vein thrombosis related to vascular access, and infection may be consequences of using these devices, none of which were reported in our observation.[13] Beside device-based techniques, despite greater pain and morbidity, open surgery is a safe and effective procedure; however, due to development of device closing techniques, surgical ligation or division of the PDA remains the treatment of choice for the rare very large ductus. As shown in our survey, despite no reported complications related to the device closure group, the open surgical ligation method was accompanied with 2.1% and 3.1% early mortality and morbidity rates, respectively. Mavroudis et al. reported the surgical procedural success rate to be 100% with a morbidity rate of 4.4% and mortality rate of 0% in a single-institution cohort over a 46-year period.[13] Similar morbidity and mortality rates have been seen in other patient cohorts, and a general estimate of the surgical mortality rate is < 0.5%.[13-16]

Reviewing the literature has shown that the closure rates of surgical ligation has been estimated to be 94% to 100% comparable with device-based methods, but with up to 2.0% mortality rate.[17-19] In our experience, the main surgery-related complications included pneumonia, pneumothorax, seizure, and some electrolyte abnormalities, including hyponatremia and hypocalcemia. According to previous reports, the major complications of open surgery are bleeding, pneumothorax, infection, and, rarely, ligation of the left pulmonary artery or aorta. Recently, due to the development of transaxillary muscle-sparing thoracotomy and the technique of video-assisted thoracoscopic ligation of the PDA, morbidity rate has been reduced, hospital stay has shortened, and cost-effectiveness of surgery has increased.[20,21]

In conclusion, although open surgery seems to be less expensive than the device closure technique, because of its lower mortality and morbidity rate, the latter technique is more preferable.

Conflict of Interests

Authors have no conflict of interests.

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