Cost-effectiveness analysis of different devices used for the closure of small-to-medium-sized patent ductus arteriosus in pediatric patients

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ABSTRACT

Aims : **In this study, we examined the differences in cost and effectiveness of various devices used for the closure of small to medium sized patent ductus arteriosus (PDA).**

Setting and Design : **We retrospectively studied 116 patients who underwent closure of small PDAs between January 2010 and January 2015.**

Subjects and Methods **Three types of devices were used: the Amplatzer duct occluder (ADO) II, the cook detachable coil and the Nit Occlud coil (NOC). Immediate and late complications were recorded and patients were followed up for 3 months after the procedure.**

Statistical Methods : **All statistical calculations were performed using Statistical Package for the Social Science software. *P* <0.05 were considered significant.**

Results : **We successfully deployed ADO II devices in 33 out of 35 cases, cook detachable coils in 36 out of 40 cases and NOCs in 38 out of 41 cases. In the remaining nine cases, the first device was unsuitable or embolized and required retrieval and replacement with another device. Eleven patients (9.5%) developed vascular complications and required anticoagulation therapy. Patients who had hemolysis or vascular complications remained longer in the intensive care unit, with consequently higher total cost (*P* = 0.016). Also, the need for a second device increased the cost per patient.**

Conclusions **The cook detachable coil is the most cost-effective device for closure of small-to medium-sized PDAs. Calculations of the incremental cost-effectiveness (ICE) revealed that the Cook detachable coil had less ICE than the ADO II and NOC. The NOC was more effective with fewer complications.**

Keywords : Amplatzer duct occluder II, cook detachable coil, cost-effectiveness, Nit Occlud coil, patent ductus arteriosus

INTRODUCTION

Health-care expenses represent a challenge in many developing countries. Currently, medical cost-effectiveness (CE) studies integrate the cost of treatment and measurements of changes in health-related quality of life after medical intervention and years of life (YOL) gained to estimate the cost of a quality-adjusted life-year (QALY).[1] Over the past four decades, a number of coils/devices have been used for the percutaneous

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closure of patent ductus arteriosus (PDA)[2] with satisfactory results and minimal complications.[3] To date, the most efficacious and cost effective closure device has not been determined.[2]

We performed a retrospective review of patients who underwent transcatheter PDA closure to compare the efficacy of various devices in a tertiary care center with limited health resources while focusing on CE.

SUBJECTS AND METHODS

This is a retrospective study of pediatric patients who underwent PDA device closure in our institute using various device types for small PDAs from January 2010 to January 2015. We compared the three commonly used devices in our center, namely the cook detachable coil (Cook Medical, Bloomington, IN, USA), the Amplatzer duct occluder (ADO) II device (AGA Medical Corporation, St. Jude Medical Inc., Minnesota, USA) and the Nit Occlud coil (NOC) (Pfm Medical, Cologne, Germany).

The study protocol was approved by our institutional ethical committee. Patients were selected for device occlusion who weighed >5 kg and who presented clinical and echocardiographic features of PDA.

The patients' medical records were reviewed, and the following data were included: demographics and associated cardiac lesions, PDA size (diameter and length) and shape according to transthoracic echocardiography and angiography, hemodynamic data, procedural details including complications and follow-up echocardiography data in the first 3 months postprocedure. The follow up echocardiogram was reviewed for a residual shunt, coil/device embolization, left pulmonary artery (LPA) stenosis (velocity >2 m/s), or coarctation of the aorta (CoA) (velocity >2 m/s).

Procedural technique

Informed consent was obtained prior to the procedure. The procedures were performed under general anesthesia. Aortography was performed to delineate ductal anatomy and size. A retrograde and/or ante-grade approach was used. The techniques of device deployment were similar to those reported in the literature.[4,5] A repeat aortogram was performed 10–15 min following device deployment. And transthoracic echocardiography was performed the following day.

Cost analysis

The costs (device cost and hospital stay costs) were obtained according to the Egyptian health insurance, the Egyptian Ministry of Health reimbursement values, and our hospital pricing lists for percutaneous PDA closures in 2014. The total cost was calculated manually for each patient. Considering that all costs fall within the past 5 years, we did not adjust the costs for inflation or discount rates, nor for indirect costs related to procedures, such as expenses occurred by the blood bank and the loss of working days by parents.

Estimates of survival and the cost-effectiveness analysis

The life expectancy for Egyptians was obtained from the life expectancy table for the Egyptian population in 2011, provided by the Egyptian Ministry of Health.[6] An estimate of the YOL gained for individuals who reached the age of 2 years (the mean age in our study) was calculated.

Cost-effectiveness ratio and incremental cost-effectiveness

The CE ratio of an intervention can be calculated by dividing the change in cost due to the application of an intervention by the change in health benefits.[7] Effectiveness is defined as a clinically meaningful event experienced by a patient, such as survival time (YOL), QALYs, or symptom-reduced days.[8] The choice of various treatment regimens for the same condition that are mutually exclusive interventions are based on the additional benefit to be gained from one therapeutic intervention compared to the alternatives. To apply this concept, incremental CE ratios (ICERs) are used. The general equation for calculating ICERs is:

$$\text{ICER} = \frac{\text{Difference in costs between the two procedures}}{\text{Difference in costs between the two procedures}}$$ [9]

In our study, the CE ratio and the ICER were calculated under the following assumptions: the life expectancy of patients with successfully treated PDA is equal to that of the general population; this life expectancy is earned, regardless of the method employed for PDA closure, provided there is no significant residual shunt, similar to the assumptions of Costa *et al.*[1] Furthermore, the CE ratio and the ICER were calculated again considering the complications as factors affecting the quality of well-being (QWB) of the patients in the short-term to calculate the QALY gained. Values for the QWB were obtained from the QWB scores for PDA closure by Gray and Weinstein.[10] We performed the calculations once based upon the minimum value of the QWB (thus, the lower QALYs) and once based on the mean value of the QWB. The ICER threshold, often denoted by λ, may be understood as the upper limit of what society is willing to pay for an additional unit of health benefit.[11] The ICER can be calculated using the mean for both cost and effectiveness measures.[12]

Willingness to pay was calculated from the current reimbursement for percutaneous PDA closure by the Egyptian health insurance and the Egyptian Ministry of

Health (i.e., the Cook detachable coil). The willingness to pay was estimated to be $850,666.7/year and $11.6/YOL.

Statistical methods

The data were statistically described in terms of the mean ± standard deviation or in terms of frequencies (number of cases) and percentages, when appropriate. A comparison of numerical variables among the three device types was performed using a one-way ANOVA test with *post hoc* multiple two-group comparisons for normally distributed data or the Kruskal–Wallis test with *post hoc* multiple two-group comparisons for nonnormally distributed data. For comparing categorical data, the Chi-square test was performed. Exact tests were used instead when the expected frequency was <5. Within-group comparisons were performed using paired *t*-tests for normally distributed data, and Wilcoxon signed rank tests were used for nonnormally distributed data. A multivariate linear regression analysis was used to test for the preferential effect of the independent variable(s) on the total cost.

$P < 0.05$ were considered statistically significant. All statistical calculations were performed using Statistical Package for the Social Science; (SPSS Inc., Chicago, IL, USA) release 15 for Microsoft windows (2006).

RESULTS

Patient characteristics

A total of 44 (37.9%) males and 72 (62.1%) females were included in the study population. The patients' demographic characteristics are presented in Table 1.

According to two-dimensional echocardiography, eight patients (6.9%) had associated valvular pulmonary stenosis (VPS), and three patients (2.6%) had a small ventricular septal defect. Left ventricular (LV) dilatation was present prior to PDA closure in 56 patients (48.3%), with a mean *Z*-score of 2.26 ± 2.2, which significantly improved after PDA closure, with a mean LV *Z*-score of 0.95 ± 2.3 ($P < 0.05$) [Table 1]. Five patients (4.3%) had prior surgical PDA closure with residual flow.

Angiographic patent ductus arteriosus characteristics

According to the type of device inserted, we classified the patients into a group closed using an ADO II, which included 35 patients (30.2%), a group closed using a Cook detachable coil, which included forty patients (34.5%), and a group closed using an NOC, which included 41 patients (35.3%).

Based on the Krichenko classification, most of our patients ($n = 75$, 64.7%) had Type A (Conical PDA), for which the most common device used was the NOC (in 33 patients; 44%) followed by the Cook detachable coil (in 29 patients; 38%). The ADO II device was used in 13 (17%) patients. The devices used for various types of PDA are listed in Table 1 and Figure 1.

Procedure details

The devices were typically inserted through 5F sheaths (in 67 patients; 57.8%), and a larger 6F sheath (in 47 patients; 40.5%). Most patients in the Cook detachable coil and NOC groups needed 5F sheaths (29 [72.5%]

Table 1: Patient demographics and patent ductus arteriosus characteristics

Device type, *n* (%)	ADO II	Cook detachable coil	NOC	Total
Total	35 (30.2%)	40 (34.5%)	41 (35.3%)	116
Age (years)	2.78±2.35	3.17±2.79	2.5±2.53	2.87±2.68
Male:female	0.25	0.82	0.86	0.61
Weight (kg)	12.4±4.9	15.33±12.9	12.1±8.1	13.47±9.7
BSA (m^2)	0.51±0.17	0.6±0.32	0.51±0.22	0.54±0.25
Narrowest PDA diameter (by echocardiography)	2.6±0.67	2.1±0.53	2.95±0.62	2.6±0.77
Narrowest PDA diameter (by angiography)	2.57±0.73	1.76±0.37	2±0.99	2.22±1
Widest PDA diameter (by echocardiography)	7±2.99	3.2±1.14	7.14±1.89	5.84±2.78
Widest PDA diameter (by angiography)	6.88±3.3	3.47±1	7.47±1.6	5.97±2.75
PDA length (by angiography)	8±3.5	5.43±1.2	4.73±1.45	6.23±2.9
LV *Z* score (before PDA closure)	3.17±2.21	2.16±2.29	1.43±1.87	2.26±2.2
LV *Z* score (after PDA closure during follow up)	2.3±1.98	1.54±2.56	−0.93±0.07	0.95±2.28
PDA type, *n* (%)				
A: Conical	13 (37.1)	29 (72.5)	33 (80.5)	75 (64.7)
B: Elongated conical	5 (14.3)	7 (17.5)	7 (17.1)	19 (16.4)
C: Tubular	5 (14.3)	2 (5)	0	7 (6)
D: Fusiform	12 (34.3)	2 (5)	0	14 (12)
E: Bizarre	0	0	1 (2.4)	1 (0.9)

PDA: Patent ductus arteriosus, ADO: Amplatz duct occlude, NOC: Nit Occlud coil, BSA: Body surface area, LV: Left ventricular

and 26 [63.4%] patients, respectively) followed by 6F sheaths in 11 (27.5%) and 14 (34.2%) patients, and only one patient (2.4%) in the NOC group required a 7F sheath. The ADO II devices were inserted through 6F sheaths in 21 patients (60%), through 5F sheaths in 13 patients (37.1%) and through a 7F sheath in one patient (2.9%).

Concomitant balloon dilatation of the VPS was performed in eight patients.

Outcomes

A summary of unsuitable devices and device dislodgment is presented in Table 2. All dislodged devices were successfully retrieved and replaced with either a larger device of the same type or another type.

Immediate residual flow was detected via angiography in 54/116 (46.6%) patients with a significant difference among the three groups ($P < 0.05$), whereas residual flow during the follow-up echocardiography (after 3 months) was detected in 22/116 (19%) of patients. Although the Cook detachable coil group had the highest number of patients with persistent residual PDA flow, the difference among the three device groups was not statistically significant ($P = 0.087$) [Table 2].

Complications

There was no mortality in any group. The mean hospital stay was 1.77 ± 0.97 days, with a mean of 1.5 ± 0.87 days in the NOC group, 1.8 ± 1.1 days in the coil group and 2 ± 0.95 days in the ADO II group. Table 2 summarizes all of the reported complications. When the variables that affect the total cost were studied, the device type, the need of another device ($P < 0.05$), fluoroscopy time ($P < 0.05$), arterial thrombosis ($P = 0.025$), and hospital stay ($P = 0.016$) were significantly positively correlated with the total cost. These results are shown in Table 3.

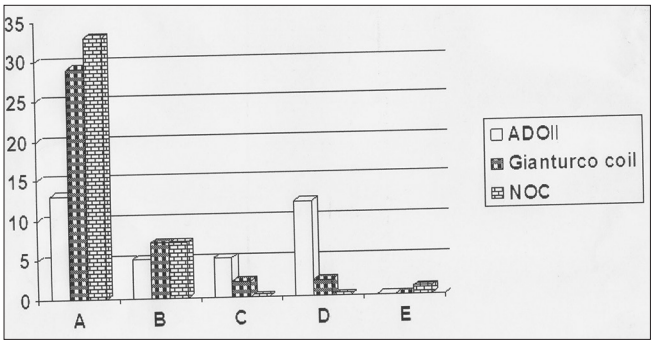

Figure 1: Types of devices used to treat various patent ductus arteriosus

Cost-effectiveness analysis

The total cost of the ADO II device was significantly higher than the costs of the Cook detachable coil and the NOC. The Cook detachable coil corresponded to the best CE, with a mean CE ratio of 11.3$/YOL, followed by the NOC with a mean CE ratio of 13.7$/YOL, whereas the ADO II device corresponded to the worst CE, with a mean CE ratio of 25.5$/YOL. The Cook detachable coil and the NOC had similar CE results. However, although the Cook detachable coil performed the best in terms of cost, when complications (at immediate and short-term follow up) were considered, the NOC performed better in terms of effect.

The CE ratio was calculated using the values of QALY gained, again revealing similar values for the Cook detachable coil and the NOC, with mean CE ratios of ~11.5$/QALY and 13.9$/QALY, respectively. The ADO II device performed worst, with a mean CE ratio of 26.5$/QALY. There were a statistically significant differences in the mean CE ratio of ADO II compared to both the Cook detachable coil ($P < 0.05$) and the NOC ($P < 0.05$). The mean CE of the NOC group was not significantly different from the CE of the Cook detachable coil group ($P = 0.193$).

Finally, we found that the NOC exhibited the best the incremental CE (ICE), whereas the Cook detachable coil corresponded to the best cost. The ICE ratio was calculated for each device in comparison to the previous device, and the Cook detachable coil corresponded to the best ICER, followed closely by the NOC [Table 3].

Table 2: Complications of transcatheter patent ductus arteriosus closure for various device groups

Complication	ADO II (%)	Cook detachable coil (%)	NOC (%)	Total (%)	*P*
Immediate					
Unsuitable/dislodged device	2 (5.7)	4 (10)	3 (7.3)	9 (7.8)	0.78
Hemolysis	3 (8.6)	3 (7.5)	0	6 (5.2)	0.17
Vascular complications	5 (14.3)	3 (7.5)	3 (7.3)	11 (9.5)	0.12
Arterial thrombosis	3 (8.6)	1 (2.5)	1 (2.4)	5 (4.3)	0.21
Residual PDA	5 (14.3)	26 (65)	23 (56.1)	54 (46.6)	<0.05
Follow-up					
Coarctation	3 (8.6)	0	0	3 (2.6)	0.056
LPA stenosis	3 (8.6)	0	1 (2.4)	4 (3.5)	0.074
Residual PDA (by echo)	5 (14.3)	12 (30)	5 (12.2)	22 (19)	0.087

PDA: Patent ductus arteriosus, ADO: Amplatz duct occlude, NOC: Nit Occlud coil, LPA: Left pulmonary artery

Table 3: The effect of different variables on the total cost

Constant	Unstandardized Coefficients		Standardized Coefficients	*t*	*P*
	B	Std. Error	Beta		
	8,129.926	3,210.217		2.533	0.013
Device 1type	-1,842.752	314.159	-0.383	-5.866	0.000
D-dislodgment	386.351	2,164.339	0.024	0.179	0.859
Device-2 need	6,315.923	1,937.278	0.435	3.260	0.002
Res-Angio	-662.204	557.580	-0.085	-1.188	0.238
Res-Echo 1	-438.998	527.600	-0.066	-0.832	0.407
Enchr-LPA	537.787	561.947	0.049	0.957	0.341
CoA	738.426	621.166	0.062		208.165
Fluoro Time				4.361	0.000
Irradiation	-79.234	56.278	-0.154	-1.408	0.162
Hemolysis	-1,277.531	969.705	-0.110	-1.317	0.191
Vascular Complications	1,675.127	1,104.103	0.136	1.517	0.132
hospital stay	754.400	307.711	0.241	2.452	0.016
Res-Echo 2	330.917	664.820	0.036	0.498	0.620
Approach	72.624	295.378	0.014	0.246	0.806

DISCUSSION

In this study, we compared the efficacy and safety profiles of the three most common devices used in our center for treatment of PDA, namely the Cook detachable coil, the ADO II device and the NOC, focusing on their CE profiles.

Previous studies have reported immediate PDA occlusion rates using Cook detachable coils varying from 59% to 93%.[2,13-19] At 6 month follow-up, closure rates of 84% and 91% have been reported,[2,17] and a closure rate of 95% has been reported at 1 year.[18] For NOCs, immediate occlusion rates of 48.4% and 71% have been reported, rising to 98% and 93% by 6 months, respectively.[2,20] In our series, we noted lower immediate closure rates for use of the Cook detachable coil (35%), whereas the NOC (43.9%) had rates comparable to those reported by Ghasemi *et al.*[2] Our 3-month occlusion rate was higher for use of the NOC (87.8%) compared to the Cook detachable coil (70%), but the difference was not statistically significant. We assume that our immediate and 3-month follow-up complete occlusion rates may be lower partly because the procedures were not performed aggressively by using multiple coils to achieve complete PDA occlusion before the procedure was terminated and also due to differences among the operators.

Regarding the ADO II devices, the previously reported immediate closure rates ranged from 95.9% to 100%.[21-23] The Liddy group reported an occlusion rate of 98% after 6 months.[22] In our study, we noted a lower immediate occlusion rate (85.7%), and this rate remained the same after 3 months. This difference may be due to the shorter time of follow-up and use of a smaller patient sample.

Device embolization has been considered to be the most significant complication of interventional PDA occlusion.[15,24,25] Device malposition or embolization was noted in some of our patients, and the highest rate corresponded to the Cook detachable coil (10%), followed by the NOC (7.3%) and the ADO II device (5.7%). The reported embolization rate for Cook detachable coils varied from 9.2% to 23%, with the highest incidence reported by the Shrivastava group.[2,26] The NOC embolization rate described by the Ghasemi group was 2%,[2] whereas the Liddy *et al.* and Masri *et al.* groups reported no device embolization with the ADO II device.[22,23]

Significant hemolysis after device deployment is rare and is primarily attributed to residual shunts, which is primarily due to the mechanical injury of red blood cells.[3] The reported rate of hemolysis varies from 0% to 3.5%.[27,28] In our study, hemolysis occurred in a total of 6 patients (5.2%), comprising 3 patients (8.6%) in the ADO II group and three patients in the Cook detachable coil group (7.5%). The Jang *et al.* group reported hemolysis in two (1.7%) of their patients who had Cook detachable coils.[3] The Masri *et al.* group did not report hemolysis among their series.[23] A possible explanation for the hemolysis noted with ADO II devices is the presence of residual PDA flow, exaggerated by the use of heparin and streptokinase for the treatment of arterial thrombosis.

Our overall rate of device protrusion into the aorta was 2.6% (3/116), which is similar to that observed in other studies.[2,3] All three patients who exhibited mild CoA had the ADO II device (8.6%). Mild LPA stenosis was noted during follow-up in 8.6% of the patients with ADO II devices and in 2.4% of patients with NOCs. However, the Ghasemi group reported coarctation of aorta (CoA) in one patient with the NOC (0.7%) and LPA stenosis in two (1.7%) patients with Cook detachable coils and one patient (0.7%) with the ADO device.[2] The Baspinar *et al.* group reported CoA in 4 patients (5.2%) with the ADO II device and LPA stenosis in 2 patients (2.6%).[21] However, the Liddy *et al.* and Masri *et al.* groups reported higher rates of CoA (14.3% and 16%) with ADO II devices without LPA stenosis.[22,23]

Despite the versatility of the ADO II and its smaller caliber delivery systems, its use was correlated with a higher complication rate. The device's flexible configuration has negative effects. The Forsey group stated that the flexible structure of the ADO II might cause tilting of the aortic disc and increase the risk of iatrogenic CoA.[29] ADO II device protrusion into the left pulmonary artery or the descending aorta is a possible complication of the procedure, although several studies have described the safety and efficacy of the device.[29-35]

However, compression of the surrounding structures was observed more frequently in younger children who received the ADO II device. Indeed, the three cases that developed mild CoA following the ADO II device had a mean weight of 8 kg. Likewise, Baspinar *et al.* noted similar findings in a study of children weighing <10 kg.[21] The probability of vascular complications is increased in young infants depending on the size of the delivery system used.[21]

Our overall rate of arterial thrombosis was 4.3% (5/116), with the highest rate noted for the ADO II group 8.6% (3/116). The Masri *et al.* and Baspinar *et al.* groups reported no significant vascular complications.[21,23]

Cost-effectiveness

This study sought to describe the safety and efficacy of current options for percutaneous PDA closure and to perform an analysis of incremental CE, which is important for the incorporation of a new technology in the public health system. To our knowledge, there are no published studies comparing the CE of devices used for the percutaneous closure of PDA in the literature. The ADO II device had a significantly higher CE ratio than the Cook detachable coil and NOC ($P < 0.05$). The Cook detachable coil and the NOC had similar CE values; however, the Cook detachable coil was the best in terms of cost, whereas the NOC was better in terms of effect.

The ICE was calculated to compare the CE of the NOC and the Cook detachable coil (the latter being currently reimbursed by the Egyptian health insurance and the Egyptian Ministry of Health). Notably, the ICER for the use of the NOC was higher, with approximately $84/year of life saved when the Cook detachable coil was used [Table 4 and Figure 2].

Even with a slightly elevated ICER, there are reasons for the possible incorporation of the NOC by the Egyptian health insurance and the Egyptian Ministry of Health. First, not all cases can be treated using an NOC (as considered in this study). The indications are individualized, which could increase the overall CE of the NOC, bringing the CE of the NOC to an acceptable threshold for its incorporation.

Additionally, the present cost analysis considered only the direct costs of the procedure, whereas indirect costs, which are more difficult to estimate, were nullified and were considered constant among all groups. However, the higher rate of hemolysis and embolization and the higher overall hospital stay (with higher costs related to the blood bank) for the Cook detachable coil are significant. In addition, the longer hospitalization time hinders the rapid return of patients to their routine activities, with possible work losses for parents. Furthermore, longer hospitalization required to treat this relatively simple congenital heart defect hinders the rapid turnover of beds in centers like ours that perform catheters and surgeries for more complex heart diseases.

Table 4: Calculations of the incremental cost-effectiveness

	Total cost	Effect	Δcost	Δeffect	ICER
Step-1					
Device (using YOL)					
ADO II	457,800	2329	378,900	2006	189
Cook detachable coil	222,600	2624	−235,200	294	−799
NOC	280,100	2711	57,500	88	657
Device (using QALY minimum)					
ADO II	457,800	2292	378,900	1984	191
Cook detachable coil	222,600	2575	−235,200	283	−831
NOC	280,100	2691	57,500	116	497
Device (using QALY mean)					
ADO II	457,800	2308	378,900	1993	190
Cook detachable coil	222,600	2599	−235,200	291	−808
NOC	280,100	2697	57,500	98	589
Step-2					
Device (using YOL)					
Cook detachable coil	222,600	2624	222,600	2624	85
NOC	280,100	2711	57,500	88	657
Device (using QALY minimum)					
Cook detachable coil	222,600	2575	222,600	2575	86
NOC	280,100	2691	57,500	116	497
Device (using QALY mean)					
Cook detachable coil	222,600	2599	222,600	2599	86
NOC	280,100	2697	57,500	98	589

YOL: Years of life, QALY: Quality-adjusted life-years, NOC: Nit Occlud coil, ICER: Incremental cost-effectiveness ratio, ADO: Amplatz duct occlude

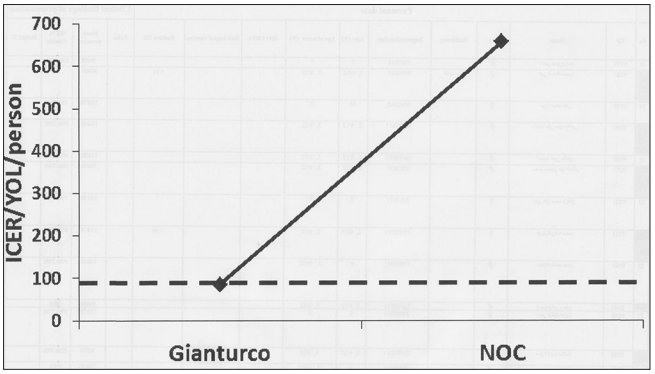

Figure 2: Incremental cost-effectiveness ratio for the most cost-effective devices

Limitations

This study has some limitations. First, this study is limited by its retrospective nature in a single tertiary center. Second, the Egyptian health insurance and the Egyptian Ministry of Health tables (currently available for the reimbursement of cardiac catheterization for the closure of PDA) need to be updated to include additional expenses, such as doctors' fees and procedural costs. Thirdly, our study does not include the ADO 1, which is widely used in other centers.

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CONCLUSIONS

Our results confirmed that Cook detachable coils are safe and correspond to an excellent ICER. PDA closure using the Cook detachable coil may be slightly less expensive than use of the NOC. However, due to its lower complications rate, the latter is preferable. Our conclusion is that NOCs are suitable for all types of PDA, and sizes up to 5 mm are especially suitable in smaller infants (<6 months and weighting <6 kg), where the use of ADO devices may be associated with a higher incidence of complications. We encourage developing countries to undertake CE studies when considering new lines of therapy.

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Conflicts of interest

There are no conflicts of interest.

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