

Comparsion between Amplatzer (Ductul occluder type 1 and vascular plug type2) in closure of symptomatic patent ductus arteriosus in infant below 6kg

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مقارنه بين استخدام نوعين من الغلاقات لغرض أغلاق النواسير في الاطفال دون عمر السنة ووزن أقل من 6 كيلو غرام

الخلاصة:

خلفية الدراسة: أن عملية أغلاق النواسير القلبية بواسطة التداخل القسطاري تطورت سريعا وهناك أنواع كثيرة من الغلاقات توفرت الآن. وقد أصبحت عملية التداخل القسطاري لأغلاق النواسير القلبية اليوم هي البديل للتدخل الجراحي و بنسبة مضاعفات أقل من التدخل الجراحي هدف الدراسة:بيان دور وفعالية نوع من الغلاقات لأغلاق النواسير المتوسطة وكبيرة الحجم مع مقارنه للنوع الاخر من السدادات

المرضى وطريقة العمل:دراسة أجريت في المركز العراقي لأمراض القلب من شهر حزيران 2012 الى شهر حزيران 2013 لثمانية وسبعين مريض من الاطفال دون عمر السنة ووزن أقل من ستة كيلو غرام ولديهم ناسور ولادي وأجريت لهم عملية أغلاق الناسور باستخدام نوعين من الغلاقات

النتائج: ثمانية وسبعين مريضا دون عمر السنة وبمتوسط وزن 4.32 كيلو غرام وبمعدل وزن (2.75-6.5) وبمتوسط عمر 7.53 شهر وبمعدل عمر (2-11.5), النسبة الكبيرة منهم كانت أنثى (55.1%) و(49.1) ذكورا وكانت نسبة النجاح لعملية التداخل القسطاري في أغلاق الناسور مهما كانت نوع السداده المستخدمه هي 87.2% والفشل هي 12.8% أما بالنسبة لأحد السدادات هي 75.6% والفشل هي 24.4% والسبب بالفشل هو عمل تضيق الشريان الأبهر في 70% أو الشريان الرئوي الأيسر في 10% من الحالات الفاشله نتيجة بروز السداده في ذلك الشريان و 20% مشاكل في الشرايين للأطراف وبالنسبة للسدادات التي فشلت تم أغلاها جميعا بواسطة السداده النوع الثاني فلذلك كانت نسبة النجاح هي 100% , لقد تم أستخدام الوريد فقط للدخول في السداد النوع الاول اما السداده النوع الثاني تم الدخول أما عن طريق الوريد 83.8% أو الشريان 16.2% كل المرضى المشمولين كانوا أيضا يعانون من ارتفاع ضغط الشريان الرئوي وبدرجات متفاوتة فقد كانت النسبة الكبيرة شديدا 53.9% ومتوسط الشده في 34.6% وبسيطا في 11.5% وأكثر الاجام المستخدمه للنوع الاول هي 6/8, 8/10 ملليمتر أما بالنسبة للنوع الثاني فكات الاحجام 8 و 10 ملليمتر الأكثر استخداما وقد وجد بأن أهم مؤثر للنجاح والفشل هو نوع وحجم السداده ووزن الطفل من المتغيرات الاخرى

الاستنتاج: بالرغم أن عملية أغلاق النواسير القلبية ممكنه بالغلاقه من النوع الاول لكن بوجود صعوبات ومشاكل تعيق عملة الاغلاق للناسور لذلك يجب البحث عن سداده خاليه من تلك المشاكل والسداده النوع الثاني أسهل الاستخدام وأرخص سعرا وبنسبة مشاكل وصعوبات قليله

Abstract

Background: transcatheter closure of patent ductus arteriosus (PDA) evolve rapidly and there are many changes in design of device using for closure, percutanouse transcatheter PDA closure in symptomatic infant as an alternative method for surgery with less complication

Objective: to evaluate the safety and effectiveness of vascular plug type 2 in closure of moderate to large PDA in compare to ADO1so increase the chance of transcatheter PDA closure in such age and weight instead of surgical closure which difficult and high risk of death in our country

Patient and method: Seventy-eight infants below 6kg of weight with symptomatic PDA visited the Iraqi center for heart disease from June 2012 to June 2013 transcatheter closure was attempted with either ADO1 or AVPs type 2 randomly

Result: Data collected from 78 babies (mean weight 4.32 kg, range: 2.75-6.5; mean age 7.53 months, range: (2-11.5) of them 55.1% female and 49.1% male ,those babies divided in two group randomly 37 cases(47.4%) trial for closed by AVPs type 2 and 41cases (52.6%)trial for closure by ADO 1 the Implantation of occluder was successful for total cases whatever the type of occluder used was 87.2% where as the success rate for cases closed by ADO1 were 31cases 75.6% and failure to closure in 10 cases 24.4% the cause behind that failure were in 70% of failure aortic obstruction, small peripheral vein in 20% and left pulmonary artery obstruction in 10% , all failed cases to close by ADO1 reclosed by AVPs type 2 so the success rate for cases closed by AVPs was 100% one cases closed by AVPs embolized and easily retrieve then replaced by larger size in same session, all cases of ADO 1 closed from antegrade rout while AVPs in (83.8%) from antegrade route and (16.2%) from retrograde route, the cases divided into three group according to degree of pulmonary hypertension, 11.5% as mild degree of PHT, 34.6% with moderate degree of PHT and 53.9% severe degree of PHT, the most size of ADO1 occluder used are (10/8mm in 53.7% and 8/6mm in 43.9%) while in vascular plug (8mm in 54.1% and 10mm in 32.4%) the most effective variable of failure or success were the weight of patient ,type of occluder and size of occluder

Conclusion: although percutaneous transcatheter closure of PDA with ADO1 if feasible and effective in infant with symptomatic PDA but with high rate of complication so we must look for new occluder this occluder that solve the problem is AVPs type 2 which cheaper, more effective and safer with more soft delivery system and easily to retrieve if embolized.

Key words: Patent ductus arteriosus, infant below 6Kg of weight, vascular plug type 2, ADO1

Introduction

Patent ductus arteriosus (PDA) is the second most common form of congenital heart defect [1], as isolated lesion represents about 9-12% of all congenital heart disease [2]. Transcatheter closure of patent ductus arteriosus (PDA) is increasingly performed worldwide, and generally surgery is now reversed for those in whom transcatheter closure is either not possible or fails [3]. Transcatheter closure was introduced by Porstmann in 1967.since then many devices designed to occlude PDA have been developed. However, most of these devices are associated with major drawbacks, including a high incidence of residual shunt and/or embolization, complex delivery system and the need for a large

delivery sheath [4]. The Amplatzer vascular plugs (AVPs) are devices that are excellent alternatives to other existing device for embolization of medium to large vascular communication. Since their introduction, there has been an exponential growth in utilization of AVPs for the closure of various intra- and extracardiac vascular communication. With the increasing need for these devices, the AVPs have evolved to great extent .As a result, currently four generation of AVPs, with different shape and occlusion properties, are available [5].

Material and method

The study was done in Iraqi center for heart disease from June 2012 to June 2013 on infants with weight less than 6kg, who underwent percutaneous closure of

significant PDA by two different type of occluder.

The inclusion criteria consisted of clinically symptomatic PDA in infants' with weight equal or less 6kg with reversible pulmonary hypertension. Symptoms of significant PDA included difficulty in breathing, recurrent respiratory tract infection, weight stagnation failure to thrive or symptoms and signs of heart failure or transthoracic echocardiography feature of significant PDA included left atrial and left ventricular volume overload and sign of pulmonary hypertension

In cardiac catheterization laboratory under general anesthesia and biplane radiographic camera in lateral view and right anterior oblique (RAO) 30 degree and sometime 70 degree left anterior oblique and 20 degree cranial view determine the shape and size for PDA the patients were divided in two groups randomly. one group closed by Amplatzer ADO type 1 occluder and the second group closed by Amplatzer AVP s type 2 the size of occluder about 1-2mm more than the PDA diameter measured by angiography except in case of severe degree of pulmonary hypertension we chose 2-4mm larger than the diameter of PDA to avoid embolization of device.

After implantation of device another angiography were done to detect the residual shunt and at the same time PA angiogram from side arm of long sheath of occluder were done to detect any obstruction of pulmonary artery branches and finally gradient measure at aortic and

pulmonary end of device to avoid any obstruction and in case of severe degree of pulmonary hypertension measure aortic pressure and pulmonary artery pressure to look for changes in pressure after closure of PDA. The stability of device was tested by pulling and pushing gently on delivery cable to document the implantation stability

The follow up for patients was done regularly on first day after implantation and seven days later and after one month then after three months and 6months and one year to detect any complication

All patients were treated with preproctural intravenous dose of Cefotaxim (50mg /kg) as well as an additional two doses after procedure within 24hours.

Results

Between October 2012 and June 2013, we select 78 infants (55.1%) girls and (44.9%) boys underwent attempted transcatheter occlusion of significant PA. The age of patients was ranging between (2-11.5) months with mean $\pm$ SD (7.53 ± 2.15) and weight in kg range from (2.75-6.5) kg with Mean $\pm$ SD (4.32 ± 0.87). The patients was divided in two groups randomly of them 37 neonates for closure by Amplatzer AVPs type 2 occluder (47.4%) and 41 neonates were closed by Amplatzer ADO type 1 (52.6%), in all patients defects close by ADO1 from venous side (antegrade) only, but in vascular plug we closed the defect from venous side (antegrade) in (83.8%) and from aortic side (retrograde) in (16.2%)

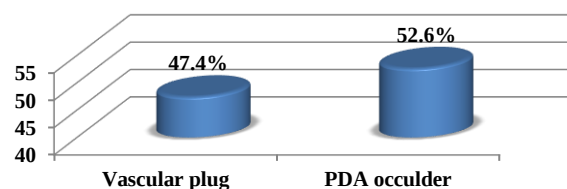


Figure 1: Distribution of patients according to method of closure

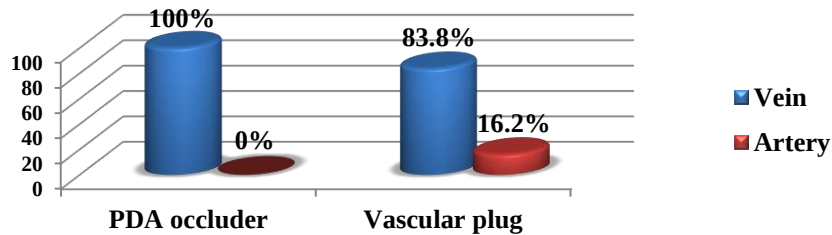


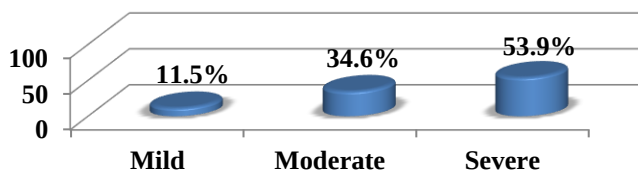
Figure 2: Distribution of patients according to method for closure and site of entrance

All patients in the study had different degree of PHT of them (11.5%) had mild degree of PHT and (34.6%) moderate degree of PHT and the largest group (53.9%) with severe degree of PHT

Figure 3: Distribution of patients according to degree of pulmonary hypertension

For all patients whatever the way of closure the success rate was (87.2%), ADO1 was implanted in 31/41 cases (75.6%) and failed in 10 patients (24.4%). The size of device used in successful closure of ADO 1 occluder 10/8mm in 17infant (25%) and 8/6mm in 13 infant (19.1%) and 6/4mm in one patient (2.4%), the size of occluder that

and cause gradient more than10mmhg and in 20% small peripheral vein that cannot pass the delivery system of ADO 1 occluder and 10% cause left pulmonary artery stenosis due to protrusion pulmonary artery disc to left pulmonary artery. Regarding the vascular plug the success rate was 100% and size of occluder used in study10mm device in



failed were 5cases 10/8mm(50%) and 5 cases 8/6mm(50%) the cause of failure were 70% due to aortic obstruction from protrude the aortic disc of occluder in aorta immediately after deployment which easily retrieved and replaced by larger size device. All failed cases in ADO1were closed by vascular plug.

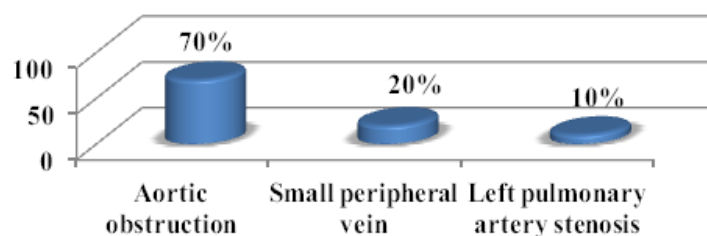


Figure 4: Outcome of PDA occluder

Figure 5: Distribution of patients with closure failure according to cause of failure

Table 1: Distribution of patients according to method of closure and size of occluder

Size of occluder	PDA occluder	Vascular plug
10/8 (mm)	22 (53.7%)	0 (0.0%)
8/6 (mm)	18 (43.9%)	0 (0.0%)
4/6 (mm)	1 (2.4%)	0 (0.0%)
10 (mm)	0 (0.0%)	12 (32.4%)
8 (mm)	0 (0.0%)	20 (54.1%)
6 (mm)	0 (0.0%)	5 (13.5%)
Total	41 (100.0%)	37 (100.0%)

We found that there were no associations between gender or degree of PHT and site of entrance on outcome of procedure but there is significant association between type and size of occluder as shown in table 2

Table 2 Association between operation outcome and study variables

Study variables	Operation outcome		P-value
	Failure (%)	Success (%)	
Gender			
Male	2 (20.0)	33 (48.5)	0.171
Female	8 (80.0)	35 (51.5)	
Method of closure			
Vascular plug	0 (0.0)	37 (54.4)	0.001*
PDA occluder	10 (100.0)	31 (45.6)	
Pulmonary hypertension			
Severe	8 (80.0)	34 (50.0)	0.097
Mild to moderate	2 (20.0)	34 (50.0)	
Site of entrance			
Femoral vein	10 (100.0)	62 (91.2)	1.000
Artery	0 (0.0)	6 (8.8)	
Size of occluder			
10/8 mm	5 (50.0)	17 (25.0)	0.001*
8/6 mm	5 (50.0)	13 (19.1)	
Other size	0 (0.0)	38 (55.9)	

There was no relation found between ages of patients but there was significant relation between type of occluder and weight of patient in the procedure

Table 3: The mean differences of age and weight by method applied for closure

variables	outcome	N	Mean $\pm$ S.D	t-test	P value
Age	PDA occluder	41	7.65 $\pm$ 1.83	0.508	0.613
	Vascular plug	37	7.40 $\pm$ 2.48		
Weight	PDA occluder	41	4.52 $\pm$ 0.85	2.265	0.026*
	Vascular plug	37	4.08 $\pm$ 0.86		

Discussion:

In this study we did Percutaneous closure of symptomatic PDA with pulmonary hypertension in infants whose weight less than or equal to 6kilogram with two different type of occluder as ADO1 or AVP2 which was feasible and effective with success rate as total for both type of occluder (87.2%) and the success rate for group closed by AVP 2occluder was 100% but for group closed by ADO1 was (75.6%)

Sylvia et al [4]in France in 2009 when use ADO for closure of PDA in infant with weight equal or less than 6kilogram the success rate for closure of (89.7%) and the failed cases referred to surgery but in our study the failed cases can closed all by AVP2 with no difficulty. Most of cases were female about (55.1%) and male (44.9%) this sex difference for such type of congenital heart diseases is same for study of Maad Ullah et al [6]study in 2012 with male to female ratio 0.8:1 ,certain type of CHD have female sex predilection one of them is PDA

The age of infants in our study range between (2-11.5) months with mean for age (7.53 $\pm$ 2.15) and weight range between (2.75-6.5) kilograms with mean (4.32 $\pm$ 0.87) and smallest weight and age of baby closed by PDA ADO1 and AVPs occluder 3.5kg and 2.750kg with age 5months and 2months respectively the age and weight for our study with range of infants age and weight in Jou-Kou Wang et al [3] in 2008 but in Sylvia Abadir et al [4]the age and weight little bit more than baby in our study, Robert et al [7] report their study in using of PDA occluder for closure of PDA in 10 preterm infants with

weight 1.6-2.6kgs with 90% success rate which small sample and seem to be small size defect due to in such weight cannot use large delivery system for ADO1 to close large defect not like our study that use two different type of occluder in moderate to large PDA

In this study we compares between ADO1 and vascular plug occluder no same study would be done but there is study by Rasha et al [9]to use ADO1 and ADO2 for closure of medium to large PDA in infants,the study did from 2009 -2011 and age and weight of child more than our patient parameter and success rate for ADO1 =67.9% and ADO2=84.2 % the ADO2 had the same limitation of ADO1 and expensive regarding the cheaper price of AVPs 2 with100% success rate for closure of PDA by AVPs even those failed to close by ADO1 reclose by AVP2 and all of our cases had pulmonary hypertension(53.9% severe PHT,34.6% moderate PHT and 11.5% mild PHT) while cases with PHT in Sylvia et al [4] study there are 33cases (56.9%) with PHT , the PHT increase complexity of PDA and difficulty in close because need increase size of occluder by 2-4mm which may cause complication in 12.8% from total cases (10complication in 78cases in study) of these complication aortic obstruction in 6 of cases (7.7%) and LPA stenosis in one cases (1.3%) and small peripheral vein so cannot pass the delivery system of occluder in 3 cases(3.8%), Vijayalakshmi et al in[10] closure of large PDA in infants less than 6kg there is complication occur like aortic obstruction in 2cases (3.3%) and LPA stenosis in one cases (1.6%) and four cases (6.6%) cases vascular complication

,Sylvia et al[4] had two type of complication the small peripheral vein and aortic obstruction which account 8.6% which of them the aortic obstruction occur in six cases the complication of his study lower than our study because mean weight in his study more than our patient but these complication is lower than that of Butera et al [11] which about 16.7% all these complication in our study related to ADO1 and these complication solved when the same patient close the PDA by AVPs ,we thought when device is release there is rocking movement of retention disc of PDA occluder in aorta so the aortic disc of occluder will protrude in aorta and cause aortic obstruction, but in AVPs there is another PA retention disc that after release of AVPs occluder the PA disc prevent the aortic disc to protrude because the occluder PA and AO disc compress against each other so the occluder became shorter and disc compress against AO and PA wall without complication of PA or aortic obstruction the PA stenosis occur when pull the ADO 1 more to PA to avoid the protrusion of it in aorta and AVPs low profile and can be can delivered through usual guiding and diagnostic catheter and same size AVPs delivered through small size sheath as compared to ADO1 which distinct advantage in small kids so no vascular limitation for pass the AVPs occluder .

The most size of ADO1 occluder used 10/8mm in 22cases (53.7%), 8/6mm in 18cases (43.9%) and 6/4mm 1case (2.4%) but in Maad et al [6] study the size of occluder used 6/4mm in 33(63.5%) cases followed by 8/6mm 15 cases (28.9%)and 10/8mm in 2cases (3.8%)in our study the maximum size was 10/8mm because the majority of cases were large size with severe degree of PHT which opposite to Maad et al[6] study where the maximum size of occluder 6/4mm mean

that the majority of cases were small size defect with no PHT, and Vijayalakshmi et al [10] maximum size of occluder use 12/10mm that cases in his study same of cases in our study as moderate to large and with PHT , in case of PHT we increase size of occluder by 2-4mm especially in ADO1 to avoid embolization, in our study the AVPs occluder used 8mm(54.1%) ,10mm in 12cases (32.4%) and 6mm in 5 cases (13.5%) because the presence of pulmonary artery retention disc that prevent embolization of occluder after release so no need for over-sizing the occluder to avoid embolization.

All cases of ADO 1 close from venous site but AVPs can close from aortic or venous side by single puncture allowing the procedure to be simple and rapid, the small size of sheath and the shape of device from aortic and PA site is the same not like that mushroom shape of ADO1 that limit the closure only from venous site, in 6cases (16.2%) the PDA close from venous site and 31cases (83.8%) from aortic site by AVPs

We found there is a strong relationship between outcome of procedure and type of occluder when more success with vascular plug than ADO1 ,regarding ADO1 the size of occluder limiting factor for success with failure in larger size of occluder because the larger occluder mean more complication occur from large delivery sheath and their more chance for causing aortic and PA obstruction , high association between outcome and weight of baby as there is a direct relationship between weight of baby and isthmus of aorta so less weight the smaller the aortic isthmus more chance for aortic obstruction and if we pull the occluder more to PA side to avoid aortic obstruction we increase the chance of PA obstruction which the same study of Sylvia et al [4]when found there is relation between weight of baby

and failure of occlusion from aortic protrusion of occluder.

The ADO2 have relatively same shape of AVP2 but the same limitation ADO1 as not use in those below 6kg and 6months, not only our study try to use the ADO1 in baby less than 6months and 6kg but there is no study compare the use of AVPs type 2 and ADO1 in closure of PDA with same parameter in our study

Conclusion:

Transcatheter closure of symptomatic PDA in infant below 6 kg is safe and effective with low rate of complication with no limitation for infant's age or weight especially with use of vascular plug type 2

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