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ORIGINAL RESEARCH ARTICLE

# Experience of percutaneous closure of small to large patent ductus arteriosus with Nit-Occlud® device in a tertiary referral hospital in Colombia

## *Experiencia del cierre percutáneo de conducto arterioso persistente de pequeño a grande con el dispositivo Nit-Occlud® en un hospital de referencia terciaria en Colombia*

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## Abstract

**Objective:** *This study aims to report the experience and outcomes in patients undergoing endovascular closure of small to medium-size PDA with a Nit-Occlud® device in a tertiary referral hospital in Colombia.* **Methods:** *Longitudinal descriptive study, which included all patients under 18 years of age who underwent percutaneous ductal closure with Nit-Occlud® device between January 1, 2011, and February 1, 2023. Patients with associated complex congenital heart disease requiring surgical management, pregnant patients, and patients with incomplete data regarding studied variables were excluded from the study.* **Results:** *Eighty-seven patients were documented, with a mean age, weight, and height at closure of 51 months, 14 kg, and 95.83 cm, respectively. About 70% of the patients (n = 61) were female, 76% were under 6-years-old and only one patient was over 15. The average size of the ductus at the pulmonary end was 2 mm. Four of the total number of patients did not achieve PDA closure during the procedure. Of the remaining 83, complete immediate closure was achieved in 81 patients. A device exchange for a larger device was required during the same procedure in one of the cases. Two patients presented residual shunt of 0.5 mm during follow-up, and one required a new procedure for device closure 10 months later. Only one device presented repeatedly embolization to the aorta, requiring surgical removal. As a technical difficulty, one device presented repeated passage into the aorta, so it was decided to remove it before releasing it to avoid complications, and given the complex anatomy of the ductus, surgical closure was indicated. Among the complications, one patient presented a hematoma of the subcutaneous tissue in the right thigh, which improved with medical management, and no deaths related to the procedure were registered.* **Conclusions:** *Using the Nit-Occlud® device to close small to moderate-sized ductus remains a safe and effective strategy with successful closure rates at 1-year follow-up irrespective of age, weight, height, or whether it involves a small or medium-sized duct. Despite our limitations, results concerning adverse effects are comparable to those observed in multicentric studies conducted in other regions.*

***Keywords:*** *Patent ductus arteriosus. Nit-Occlud® device. Endovascular closure. Interventional devices.*

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## Resumen

**Objetivo:** *Este estudio tiene como objetivo informar la experiencia y los resultados en pacientes sometidos a cierre endovascular del CAP de tamaño pequeño a mediano con un dispositivo Nit-Occlud® en un hospital de tercer nivel de referencia en Colombia.* **Método:** *Estudio descriptivo longitudinal, que incluyó a todos los pacientes menores de 18 años a quienes se les realizó cierre ductal percutáneo con dispositivo Nit-Occlud® entre el 1 de enero de 2011 y el 1 de febrero de 2023. Se excluyeron: pacientes con cardiopatía congénita compleja asociada que requirieron manejo quirúrgico, pacientes embarazadas y pacientes con datos incompletos sobre las variables estudiadas.* **Resultados:** *Se documentaron 87 pacientes, con edad, peso y talla promedio al cierre de 51 meses, 14 kg y 95.83 cm, respectivamente. El 70% de los pacientes (n = 61) eran mujeres, el 76% tenían menos de seis años y solo un paciente tenía más de 15 años. El tamaño medio del conducto en el extremo pulmonar fue de 2 mm. Cuatro del total de pacientes no lograron el cierre del CAP durante el procedimiento. De los 83 restantes, se logró el cierre inmediato completo en 81 pacientes. En uno de los casos fue necesario cambiar el dispositivo por uno más grande durante el mismo procedimiento. Dos pacientes presentaron shunt residual de 0.5 mm durante el seguimiento y uno requirió un nuevo procedimiento para cierre del dispositivo diez meses después. Solo un dispositivo presentó embolización repetida en la aorta, requiriendo extracción quirúrgica. Como dificultad técnica, un dispositivo presentó paso repetido hacia la aorta, por lo que se decidió retirarlo antes de liberarlo para evitar complicaciones y dada la compleja anatomía del ductus se indicó cierre quirúrgico. Entre las complicaciones, un paciente presentó un hematoma del tejido subcutáneo en el muslo derecho, que mejoró con el manejo médico, y no se registraron muertes relacionadas con el procedimiento.* **Conclusiones:** *El uso del dispositivo Nit-Occlud® para cerrar conductos de tamaño pequeño a moderado sigue siendo una estrategia segura y eficaz con tasas de cierre exitoso al año de seguimiento, independientemente de la edad, el peso, la altura o si se trata de un conducto de tamaño pequeño o mediano. A pesar de nuestras limitaciones, los resultados sobre los efectos adversos son comparables a los observados en estudios multicéntricos realizados en otras regiones.*


***Palabras clave:*** *Conducto arterioso persistente. Dispositivo Nit-Occlud®. Cierre endovascular. Dispositivos intervencionistas.*

## Introduction

Patent ductus arteriosus (PDA) is one of the most frequent congenital defects in the world, representing 5-10% of all congenital heart defects[1]. Depending on the ductal diameter (DD), it may be considered small (DD ≤ 1.5 mm), moderate (DD > 1.5 and ≤ 2.5 mm), or large (DD > 2.5 mm)[2]. According to the symptoms, hemodynamic compromise, respiratory, and renal function, response to medical treatment, as well as DD, medical, or surgical management can be considered[3]. However, moderate and large PDAs benefit of premature closure to prevent progression to irreversible pulmonary disease (Eisenmenger's syndrome)[2,4]. In the case of silent ductus, the decision should always be individualized and taken together with the child's family once the risks and benefits of both choices have been exposed. In addition, the cost-effectiveness of the procedure will play an important role in the choice[5].

The first surgical closure of PDA was reported by Gross and Hubbard in 1938, and it was not until 1967 that the first endovascular closure was performed by Porstmann et al.[6,7]. Since then, different devices have been proposed, such as the Rashkind device in the 1980s, the Gianturco coils used by Cambier and Moore in the early 1990s, and the Amplatzer Duct Occluder in the late 1990s[8-11]. Around the same time, the Nit-Occlud® device was also beginning to be used in human trials, specifically for small to medium-sized canals[12]. The most notable work at that time was carried out in 1997, in a multicenter study in Europe involving 514 patients, proving a success rate of about 97% depending on the type of PDA[12]. However, only in 2013 was it approved for use by the Food and Drugs Administration (FDA) in North America[11,13], where it is valid for PDAs smaller than 4 mm in patients over 6 kg and 6 months of age[13]. It is important to note that a weight lower than the one previously mentioned has not been shown to be a contraindication for the procedure, nor has it been demonstrated to significantly increase the occurrence of adverse events[14,15].

Endovascular closure of PDA, especially with the Nit-Occlud® device, has been and continues to be an option for PDA management[13]. This study aims to report the experience and outcomes in patients undergoing endovascular closure of PDA with the Nit-Occlud® device in a tertiary referral hospital in Colombia.

## Methods

A longitudinal descriptive study was conducted, collecting ambispective data from medical records from January 2011, up until February 2023, related to closure

of persistent ductus arteriosus. All patients under 18 years of age who underwent percutaneous ductus closure with a Nit-Occlud® device at our institution were included. Exclusions were made for patients with associated complex congenital heart disease requiring surgical management, pregnant individuals, and patients with incomplete data regarding studied variables.

The variables considered in this analysis encompass various aspects, including demographic data such as age, weight, gender, and height, as well as specific procedural characteristics such as ductus length and diameter at the pulmonary end. In addition, aspects related to successful implantation, device changes, reasons for these changes, the occurrence of embolization, its location, hospitalization days, complete closure in follow-up, residual shunt at 6 and 12 months, mortality, immediate complications, and late complications are assessed.

The collected data were managed in a RedCap database under the custody of the Clinical Research Center of the institution. The quality of the data was verified by comparing it with source documents, and a univariate analysis was conducted to understand the distribution of numerical and qualitative variables. Normality was assessed using the Shapiro-Wilk test. Descriptive statistics and survival analysis using the Kaplan-Meier method were applied, with all these procedures conducted using Stata 16.1®.

Approval was obtained from the Institutional Ethics Committee, and given the study's observational nature; an informed consent waiver was requested.

### *Implantation procedure*

All procedures were performed under general anesthesia with heparin at 100 IU/kg plus antibiotic prophylaxis. Femoral venous and arterial access was obtained with 4 or 5 French catheters according to patient size. Device size selection was made based on measuring the ductus in the lateral aortogram. Subsequently, a delivery heath was swapped over the wire from the venous side. The device was carefully threaded onto the delivery cable, placed in saline, and pulled into the loader, which was afterward attached to the delivery sheath once again and the device was gently moved through the delivery sheath until the disk became visible in the aorta. Once the system was partially configured, it was retracted into the PDA. All devices were placed under fluoroscopy. The procedure was made primarily anterograde as first election, and retrograde intervention was made when canalization of PDA was not possible through the pulmonary artery. A post-implantation aortogram was performed to evaluate residual shunts and device position abnormalities, excluding obstruction in the left pulmonary artery or aorta. All patients were evaluated 24 h after the procedure to rule out local complications in puncture sites and by echocardiography. Data collection included clinical and echocardiographic follow-ups at 1 month, 6 months, and 12 months.

**Table 1.** Clinical characteristics of population

| Variables | n = 87 (%) |
|---|---|
| Gender | |
| Female | 61 (70.11) |
| Male | 26 (29.89) |
| Age (months) at closure | 51 (3-188) |
| 0-36 months | 50 (57.5) |
| 37-72 months | 16 (18.4) |
| 73-108 months | 8 (9.2) |
| 109-144 months | 5 (5.74) |
| 145-180 months | 7 (8.05) |
| 181 months | 1 (1.15) |
| Weight (kg) at closure | 14.17 (7-72) |
| Height (cm) at closure | 95.8 (65-135) |

A univariate analysis was performed to determine the behavior of the numerical variables; the normality of the variables was determined through a Shapiro-Wilk test, and those with a $p > 0.05$ were considered to have a normal distribution and are presented with averages and standard deviation, and those that were not normal are presented with median and interquartile ranges. Qualitative variables are summarized as percentages. Frequency tables were elaborated to organize and know the information stated in the objectives. Descriptive statistics were applied. All analyses were conducted using RStudio®.

## Results

Eighty-seven patients were included, with mean age, weight, and height at the closure of 51 months (range 3-188 months), 14 kg (range 7-72 kg), and 95.83 cm (range 65-135 cm), respectively (Table 1). Sixty-one (70%) female patients were included. The average ductus size at the pulmonary end was 2 mm. The most frequently used device size was 4 × 4 mm, followed by 11 × 6 mm (Table 2).

Four of the total number of patients did not achieve PDA closure during the procedure. Of the remaining 83,

complete immediate closure was achieved in 81 patients. A device exchange for a larger device was required during the same procedure in one of the cases (Table 2). Two patients presented residual shunt of 0.5 mm during follow-up, and one required a new procedure for device closure 10 months later.

Only one device presented embolization to the aorta, anchoring itself to the aortic wall and requiring surgical removal (Table 3). As a technical difficulty, we mention the case of a device that presented repeated passage into the aorta, for which it was decided to remove it before releasing it to avoid complications, and given the complex anatomy of the ductus, surgical closure was indicated.

There were no deaths related to the procedure. Among the complications, one patient presented a hematoma of the subcutaneous tissue in the right thigh, which improved with medical management. No arrhythmias, pulseless or acute limb injury, or any other complication aside from the mentioned were reported.

**Table 2.** Procedure characteristics

| Variables | n = 87 (%) |
|---|---|
| NIT Occluder: device size (mm) | |
| 4/4 | 31 (35.63) |
| 4/5 | 11 (12.64) |
| 5/6 | 11 (12.64) |
| 6/7 | 10 (11.49) |
| 6/9 | 5 (5.75) |
| 6/11 | 19 (21.84) |
| PDA diameter at the pulmonary end (mm) | 2 (1.5-4) |
| Small (DD ≤ 1.5 mm) | 28 (32.18) |
| Moderate (DD > 1.5 and ≤ 2.5 mm) | 41 (47.13) |
| Large (DD > 2.5 mm) | 18 (20.69) |
| Successful procedure | |
| Yes | 83 (95.40) |
| No | 4 (4.60) |
| Device replacement | |
| Yes | 1 (1.15) |
| No | 86 (98.85) |
| Device replacement cause | |
| Very small device | 1 (1.15) |
| Complete PDA closure | |
| Yes | 81 (93.10) |
| No | 6 (6.90) |

PDA: patent ductus arteriosus.

**Table 3.** List of complications presented

| Variables | n = 87 (%) |
|---|---|
| Device embolization | |
| Yes | 2 (2.3) |
| No | 85 (97.70) |
| Embolization site | |
| Aorta | 2 (2.3) |
| Pulmonary artery | NA |
| Hospital stay (days) | 1 (1-2) |
| Residual shunt (mm) | 0.5 (0-1) |
| Mortality | NA |
| Immediate complications | |
| Displaced/misfitted | 1 (1.15) |
| Vascular complications | 1 (1.15) |
| Late complications | |
| Residual PDA (by ultrasound) | 2 (2.30) |

PDA: patent ductus arteriosus.

## Discussion

The Nit-Occlud®, developed by PFM Medical in Cologne, Germany, is a coil-type device with a controlled release mechanism designed for the closure of small to moderate-sized PDAs[13] and although it has been approved in Europe since 2001 and by the FDA for 10 years, it is not frequently used in Latin America. This device has shown remarkable effectiveness and safety in the short-, medium-, and long-term closure of atrial and ventricular defects, with minimal to no complications during or after the intervention[16-20]. Its application in the closure of PDA yields similar results to those observed in other conditions.

For example, a multicenter study conducted in the United States in 2014 reported a composite success rate of 95.1%, with no recorded deaths or severe adverse effects, and an overall adverse event rate of 4.7%[11]. Similarly, another multicenter study published in 2018 in the same country achieved a success rate of 94.4%, with 97.4% of enrolled patients demonstrating complete echocardiographic closure at 12 months, showing trivial to no residual shunt[13]. In this case, the total adverse event rate was 1%. Nevertheless, the size population must be considered when comparing this data. In contrast, a 268-patient cohort assessed in Ukraine reported a success rate of 98.5% at 6 months, all of whom underwent successful device implantation without complications during or after the procedure. Only one thromboembolic event occurred during the complete follow-up period[21]. On the other hand, studies conducted in Portugal have proven similar success rates as the previously mentioned with a 1.8% complication rate post-procedure reported[22].

In Latin America, the closest study to ours was made in Argentina, evaluating a total of 43 patients treated with Nit-Occlud® between 2010 and 2011 from three different medical centers[23]. The device was successfully implanted in all patients, achieving full closure of the PDA in all the patients at 3 months. Only one case of embolization was registered, associated to undersizing, and was treated successfully with a larger device[23]. In our study, two devices caused embolization into the aorta. The first case required device replacement because it was too small for the patient. In the second case, repeated embolization occurred. Given the complex anatomy of the ductus, surgical closure was recommended.

This study is one of the two major studies registered in Latin America that proves the effectiveness and safety of the Nit-Occlud®. In our center, the Nit-Occlud® device stands out as one of the most frequently utilized options for closing small to medium-sized ducts. We present a 12-year experience involving 87 patients of various ages. Approximately 76% of the total patient population was under 6-years-old, with nearly 60% falling below the age of three. The remaining 24% of the studied cohort comprised patients aged 6 years or older, with only one individual exceeding the age of fifteen. The average PDA size was 2 mm, about 47% had moderate size PDA, followed by small size with 32.18% and large size with 20.69%. Only three patients had a PDA of 4 mm or more. Therefore, considering the immediate successful closure rate was 93%, with no major complications or related mortality recorded, it is possible to affirm that the device and the procedure are not only safe and highly effective but also secure, irrespective of age, weight, or height. We also found that the obtained results were independent of PDA size, proving equally useful in small, medium, and large-sized PDAs.

Consistent with previous reports, we documented minimal minor vascular complications, aligning with findings in the global literature on the use of this device, no patient reported pulseless or acute limb injury, decrease of ejection fraction post-procedure, pericardial effusion or any other[11,13,21,23]. Two patients presented residual shunt of 0.5 mm during follow-up, and one required a new procedure for device closure 10 months later. No obstruction of neighboring structures, such as the aorta or left pulmonary artery, was found in any of our patients, and no death was registered.

During follow-up, complete closure was obtained in most patients, which is usual with the use of Nit-Occlud® since its compact Nitinol coil structure promotes such closure[24]. The incidence of a residual shunt in the immediate post-operative period is also reported with the use of other devices[25], being more frequent the larger the diameter of the ductus. Post-procedure recovery was rapid in all our patients with a short hospital stay, representing an advantage over surgical closure of the ductus.

A limitation on our study stems from its single-center and ambispective design, potentially leading to the underrepresentation of minor incidents and technical challenges during the procedures. Despite this, major complications were reported, and it stands as the largest case series involving this device in Latin America. Likewise, the absence of data on ductus morphology based on Krichenko's classification in the clinical records is another potential limitation. Such data could have offered insights into the device's suitability for closure in different anatomies. Nevertheless, these limitations do not compromise the overall conclusion that Nit-Occlud® proves effective and safe, with only a few major adverse effects.

## Conclusion

Using the Nit-Occlud® device to close small to moderate-sized ductus remains a safe and effective strategy with successful closure rates at 1-year follow-up irrespective of age, weight, height, or whether it involves a small or medium-sized duct. Despite our limitations, results concerning adverse effects are comparable to those observed in multicentric studies conducted in other regions.

## Funding

None.

## Conflicts of interest

None.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research Ethics Committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

**Confidentiality of data.** The authors declare that no patient data appear in this article.

**Right to privacy and informed consent.** The authors declare that no patient data appear in this article.

**Use of artificial intelligence for generating text.** The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript or for the creation of images, graphics, tables, or their corresponding captions.

## References


1. Keane JF, Lock JE, Fyler DC, Nadas AS. Nada's Pediatric Cardiology. 2nd ed. Philadelphia, PA: Hanley and Belfus, Saunders; 2006. p. 617-25. Available from: https://www.worldcat.org/title/nadas-pediatric-cardiology/oclc/778074562?referer=di&ht=edition
2. Deng Y, Zhang H, Zhao Z, Du J, Bai R, McNamara PJ. Impact of patent ductus arteriosus shunt size and duration on risk of death or severe respiratory morbidity in preterm infants born in China. Eur J Pediatr. 2022;181:3131-40.
3. Gillam-Krakauer M, Mahajan K. Patent ductus arteriosus. In: StatPearls. Treasure Island, FL: StatPearls Publishing; 2023. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430758 [Last accessed on 2023 Oct 31].
4. Warnes CA, Williams RG, Bashore TM, Child JS, Connolly HM, Dearani JA, et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease. J Am Coll Cardiol. 2008;52:e143-263.
5. Prieto LR, DeCamillo DM, Konrad DJ, Scalet-Longworth L, Latson LA. Comparison of cost and clinical outcome between transcatheter coil occlusion and surgical closure of isolated patent ductus arteriosus. Pediatrics. 1998;101:1020-4.
6. Gross RE, Hubbard JP. Landmark article Feb 25, 1939: surgical ligation of a patent ductus arteriosus. Report of first successful case. By Robert E. Gross and John P. Hubbard. JAMA. 1984;251:1201-2.
7. Porstmann W, Wierny L, Warnke H. Der Verschluß des ductus arteriosus persistens ohne thorakotomie. Thorac Cardiovasc Surg. 1967;15:199-203.
8. Rashkind WJ, Mullins CE, Hellenbrand WE, Tait MA. Nonsurgical closure of patent ductus arteriosus: clinical application of the Rashkind PDA occluder system. Circulation. 1987;75:583-92.
9. Cambier PA, Kirby WC, Wortham DC, Moore JW. Percutaneous closure of the small (less than 2.5 mm) patent ductus arteriosus using coil embolization. Am J Cardiol. 1992;69:815-6.
10. Pass RH, Hijazi Z, Hsu DT, Lewis V, Hellenbrand WE. Multicenter USA Amplatzer patent ductus arteriosus occlusion device trial: initial and one-year results. J Am Coll Cardiol. 2004;44:513-9.
11. Moore JW, Greene J, Palomares S, Javois A, Owada CY, Cheatham JP, et al. Results of the combined U.S. Multicenter pivotal study and the continuing access study of the Nit-Occlud PDA device for percutaneous closure of patent ductus arteriosus. JACC Cardiovasc Interv. 2014; 7:1430-6.
12. Munayer Calderón JE, Aldana Pérez T, Lázaro Castillo JL, San Luis Miranda R, Ramírez Reyes H, Amaya Hernández A, et al. Cierre de conducto arterioso persistente con dispositivo Nit-Occlud: experiencia de 13 casos. Arch cardiol Méx. 2005;75:408-12.
13. Kobayashi D, Salem MM, Forbes TJ, Gordon BM, Soriano BD, Dimas V, et al. Results of the combined U.S. multicenter postapproval study of the Nit-Occlud PDA device for percutaneous closure of patent ductus arteriosus. Catheter Cardiovasc Interv. 2019;93:645-51.
14. Moysich A, Happel CM, Laser KT, Kececioglu D, Haas NA. Implantation of the new Nit□Occlud PDA□R device in children below 10 kilogram. Catheter Cardiovasc Interv. 2015;85:1203-8.
15. Bischoff AR, Jasani B, Sathanandam SK, Backes C, Weisz DE, McNamara PJ. Percutaneous closure of patent ductus arteriosus in infants 1.5 kg or less: A meta-analysis. J Pediatr. 2021;230:84-92.e14.
16. Bulut MO, Yucel IK, Kucuk M, Balli S, Basar EZ, Celebi A. Initial experience with the nit-occlud ASD-R: short-term results. Pediatr Cardiol. 2016;37:1258-65.
17. Kozlik-Feldmann R, Lorber A, Sievert H, Ewert P, Jux C, Müller GC, et al. Long-term outcome of perimembranous VSD closure using the Nit-Occlud® Lê VSD coil system. Clin Res Cardiol. 2021;110:382-90.
18. Nguyen HL, Phan QT, Dinh LH, Tran HB, Won H, Thottian JJ, et al. Nit-Occlud Lê VSD coil versus duct occluders for percutaneous perimembranous ventricular septal defect closure. Congenit Heart Dis. 2018;13:584-93.
19. Mohammed MH, Tamimi O, Al-Mutairi M, Alomrani A. Outcome of ventricular septal defect closure with the Nit-Occlud(®) Le VSD-Coil: single centre experience. Sudan J Paediatr. 2022;22:172-8.
20. Ghaderian M, Shahsanaei F, Behdad S, Mozafari S. Long-term consequences of ventricular septal defect closure using Nit-Occlud Le VSD coil device: a systematic review and meta-analysis. Heart Views. 2022;23:93-9.
21. Maksymenko A, Kuzmenko Y, Dovhaliuk A, Motrechko O, Herrmann F, Haas N, *et al.* Percutaneous closure of patent ductus arteriosus with the Nit-Occlud® patent ductus arteriosus device in 268 consecutive cases. Ann Pediatr Cardiol. 2019;12:206.
22. Antunes Sarmento J, Correia-Costa A, Gonçalves E, Baptista MJ, Silva JC, Moreira J. Percutaneous patent ductus arteriosus closure: twelve years of experience. Rev Port Cardiol (Engl Ed). 2021;40:561-8.
23. Granja MA, Trentacoste L, Rivarola M, Barbosa JD, Lucini V, Peirone A, et al. Multicenter nit-occlud® PDA-R patent. Ductus arteriosus occlusion device trial: initial and six-month results. Catheter Cardiovasc Interv. 2015;86:258-63.
24. Hiremath G, Aggarwal V, Soule K, Bass JL. Immediate angiographic residual shunt using the Nit-Occlud device for patent ductus arteriosus closure. Postepy Kardiol Interwencyjnej. 2020;16:460-5.
25. Amoozgar H, Salehi S, Farhadi P, Edraki MR, Borzoee M, Ajami G, et al. Follow-up results of device occlusion of patent ductus arteriosus. Iran J Pediatr. 2016;26:e3621.