OUTCOMES OF TRANSCATHETER DEVICE CLOSURE IN ATRIAL SEPTAL DEFECT SECUNDUM IN KELANTAN: A SINGLE CENTER EXPERIENCE

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ABSTRAK

Hasil Akhir Dari Penutupan *Atrial Septal Defect Secundum* Dengan Menggunakan Alat Melalui Transkateter Di Kelantan: Satu Pengalaman Pusat Tunggal.

Latar belakang: Melihat ciri-ciri demografi, prosedur dan klinikal pesakit-pesakit yang mempunyai *atrial septal defect secundum* (ASDs), yang telah melalui penutupan dengan menggunakan alat melalui kaedah transkateter, *median survival time* untuk penutupan ASDs dan hasil akhir pada kanak-kanak dan orang dewasa.

Metodologi: Kajian retrospektif ini telah dijalankan dari Januari 2005 sehingga Disember 2015 ke atas pesakit-pesakit yang mempunyai ASDs yang telah menjalani penutupan dengan menggunakan alat melalui kaedah transkateter di Hospital Universiti Sains Malaysia.

Keputusan: 73 pesakit (42 kanak-kanak dan 31 orang dewasa) dan 75% pesakit adalah perempuan. Median umur ketika diagnosa adalah 8 tahun, dan median umur ketika hari prosedur adalah 15 tahun. 25% pesakit mengalami simptom pada hari prosedur, dan majoriti mempunyai simptom cepat penat dan lemah (83%). Majoriti pesakit adalah dari kumpulan ASDs yang bersaiz besar (median 22mm (7mm – 33.6mm) dan 60% pesakit memiliki kekurangan rim. *Median survival time* sehingga penutupan ASDs dalam kanak-kanak adalah pada umur 3 tahun, manakala untuk orang dewasa adalah 2 tahun. Kadar kejayaan adalah 90.4%. Sisa *shunt* adalah 5.5% sebaik sahaja selepas prosedur dan tutup sepenuhnya 100% diakhir susulan pada 2 tahun.

Kesimpulan: Penutupan ASDs dengan menggunakan alat melalui kaedah transkateter adalah selamat dan efektif dalam populasi pesakit-pesakit yang memiliki ASDs yang bersaiz besar, kekurangan rim, bersama dengan hasil akhir yang setara, bersama dengan komplikasi yang rendah.

Kata kunci: *Atrial septal defect secundum*, penutupan ASDs alat kateter, kekurangan rim.

ABSTRACT

Outcomes Of Transcatheter Device Closure In Atrial Septal Defect Secundum In Kelantan: A Single Center Experience.

Background – To look at demographic, procedural and clinical characteristic of patients with atrial septal defect secundum (ASDs) who underwent transcatheter device closure, median survival time to ASDs closure and its outcome in pediatric and adult patients.

Material and methods – This retrospective study was conducted from January 2005 to December 2015 in patients with ASDs underwent transcatheter device closure at Hospital Universiti Sains Malaysia.

Results – 73 patients (42 children and 31 adults) with 75% of female predominance. Median age at diagnosis was 8 years old and median age at procedure was 15 years old. 25% of patients are symptomatic on procedural day, with reduced effort tolerance being the most reported symptoms (83%). Majority of patients had large ASDs, with median of 22mm (7mm – 33.6mm), with 60% of patients had rim deficiency. Median survival time of ASDs closure in pediatric and adult age group were 3 years and 2 years respectively. Success rate was 90.4%. There was 5.5% residual shunt immediately after procedure, with 100% complete resolution at the end of follow-up at 2 years.

Conclusions – Transcatheter device closure is safe and effective in large ASDs population with rim deficiency, with comparable outcome and minimal serious complication.

Keywords – Atrial septal defect secundum, transcatheter device closure, rim deficiency

2.0 TEXT

2.1 INTRODUCTION

Atrial septal defect (ASD) is one of the most common form of congenital heart disease, with a prevalence of 10 to 20% of all congenital heart defects with incidence of one in every 1,000 to 1,500 live births (Tobis and Shenoda, 2012; Geva *et al.,* 2014). Patients with ASD are usually diagnosed incidentally or present with symptoms such as easy fatigability, frequent lung infections and exercise intolerance. ASD secundum (ASDs) is the most common type of ASD (Tobis and Shenoda, 2012; Geva *et al.,* 2014). In a normal clinical course of ASDs, the highest number of spontaneous ASDs closure occur in patients younger than 2 years of age, especially in those with small ASDs (less than 5 mm), but not in those with moderate to large ASDs (Behjati *et al.,* 2011; Tobis and Shenoda, 2012; Geva *et al.,* 2014). The latter will remain either asymptomatic or develop pulmonary hypertension with increasing age (Geva *et al.,* 2014; Behjati-Ardakani *et al.,* 2016).

ASD has been reported as early as 1950s (King *et al.,* 1976). In the early years, surgical closure was the gold standard for the treatment of ASDs. Transcatheter method of ASDs closure was introduced later in 1974, when it was first described by King et al. Since then, a lot of advancements have been made in the use of devices to close the ASDs. Extensive studies and reviews have been done in comparing surgical method and transcatheter methods for the closure of ASDs. However, the latter has been the preferred method used worldwide (Butera *et al.,* 2011; Geva *et al.,* 2014; Villablanca *et al.,* 2017).

The purpose of this study is to look at demographic, clinical characteristic and procedural features, and to compare outcomes of transcatheter ASDs device closure in both

pediatric and adult age groups, as well as the timing of ASDs closure in pediatric patients in our institution.

2.2 STUDY PROTOCOL

2.2.1 BACKGROUND OF THE STUDY

Atrial septal defect (ASD) is one of the commonest type of congenital heart disease. ASD was reported to have a prevalence in 10 to 20% of all congenital heart defects, with the incidence of 1 per 1000 live birth. There are few types of ASDs with ASD secundum (ASDs) being the commonest, followed by ASD primum and sinus venosus. Although the majority of ASDs are sporadic in nature, they are also associated with some genetic syndromes, for example Holt-Oram syndrome and Ellis van Creveld syndrome. There is also a familial form of ASD being described, which is caused by the mutation in NKX2-5 gene, a cardiac homeobox gene which is involved in normal cardiac development (Liu *et al.,* 2011).

In a normal clinical course of ASDs, patients can go beyond childhood without any symptom. Usually they are diagnosed incidentally, with the presence of a murmur, abnormal electrocardiography, or abnormal chest X ray. Symptoms may appear during the second decade of life when they present with easy fatigability, frequent lung infection and exercise intolerance, which is due to pulmonary hypertension. According to Behjati *et al*, (2011), the highest number of spontaneous ASD closures occurred in patients younger than 2 years, although it is unlikely to happen in medium to large ASDs. The latter tend to worsen with age, with the increasing risk of developing pulmonary hypertension. They also may progress to right heart failure, if no proper treatment was given.

ASD has been reported since 1950s. In the early years, surgical closure had been the method of choice, and became the gold standard in the treatment of ASD. It has few mortality and morbidity rate, with 100% efficacy and good outcome. Transcatheter method of ASD closure however derived a bit later in 1974, when it was first described by King *et al*. Since then, a lot of different type of devices has been introduced, with equally good outcome, in the absence of a large thoracotomy scars. Extensive studies and reviews have been done in comparing surgical and transcatheter methods for ASDs closure, and the latter has been the preferred method used worldwide.

2.2.2 PROBLEM STATEMENT & STUDY RATIONALE

Although surgical ASD closure was considered as the gold standard in previous generation, it was known to be associated with higher risk intra-operatively, longer length of hospital stay post-operatively, with visible large thoracotomy scar. According to a review done by Butera *et al* (2011), a higher rate of both total and major complications related to the surgical approach was found, with 5.4 fold higher risk in this group. The length of hospital stay was 2.5 times longer in patients treated surgically.

Locally, we are still facing obstacles and limitation towards surgical intervention. We have limited centers with cardiac surgeon, limited pediatric ICU bed, limited intensivist and lack of other resources as well. Thus, in our country, transcatheter device closure has been a method of choice for ASDs closure.

The rationale of this study is to look at characteristic of our patients who underwent transcatheter ASDs device closure in Hospital USM, Kubang kerian, as there was no similar study done locally as of date. There was also limited information on the outcome of patients

from different age group. I would also like to identify the type of patients who failed device closure, and those who developed complication from the procedure in Hospital USM Kubang Kerian, and its confounding factor. There are also not many ~~s~~studies describing the waiting time for the intervention from the time of diagnosis.

The finding of this study is important to assist us in measuring our own compliance in the field of transcatheter device closure in comparison with other center internationally. The findings also help us to improve our counseling with regards to ASDs to our local patients.

2.2.3 RESEARCH QUESTIONS

1. What are the demographic and clinical characteristic of patients with ASDs who underwent transcatheter device closure in Hospital USM?
2. When is the waiting time to ASDs closure for pediatric and adult age group?
3. Is there any difference outcome between pediatric and adult with ASD?

2.2.4 OBJECTIVE

- **Primary Objective;**
    1) To describe demographic, clinical characteristic, procedural features and outcome of patients who underwent transcatheter ASDs device closure in Hospital USM.
    2) To determine the median survival time (years) to close ASDs in pediatric and adult age group in our center from the time of diagnosis.
- **Secondary objective;**

1) To compare the success rate of ASDs closure between pediatric and adult age groups.

2) To compare the complications of ASDs closure between pediatric and adult age groups.

2.2.5 LITERATURE REVIEW

Mean age at the time of procedure for children ranged from 6.7 to 10 years old (Kazmi *et al.*, 2009; Saritas *et al*., 2016). Other European cardiac centers closed ASDs at a younger age, for example Petit *et al* (2013), with mean age at closure at 2.9 years old, and O'Byrne *et al* (2014), with mean age of 5.9 years old. As for adult, the mean age at the time of procedure ranged from 34 to 39 years old (Oflaz *et al.,* 2013; Saritas *et al.,* 2016). One center had a median of 49 years old (Humenberger *et al.,* 2011). The study was done in Germany, with a majority of their patients aged more than 50 years old.

Female patients who underwent ASD closure were more common, in comparison with male patients, with a percentage of 58% to 66% (Kazmi *et al.,* 2009; Petit *et al.,* 2013).

Mean weight of pediatric patients ranged from 17kg to 23kg (Saritas *et al.,* 2016; Ali *et al.*, 2017), with the minimum mean weight of the procedure being performed at 11kg (Petit *et al.,* 2013) in the study where the closure was performed in infantile age group less than 4 years old. For the adult group, the mean weight ranged from 64kg to 68kg (Baruteau *et al.,* 2014; Saritas *et al.,* 2016).

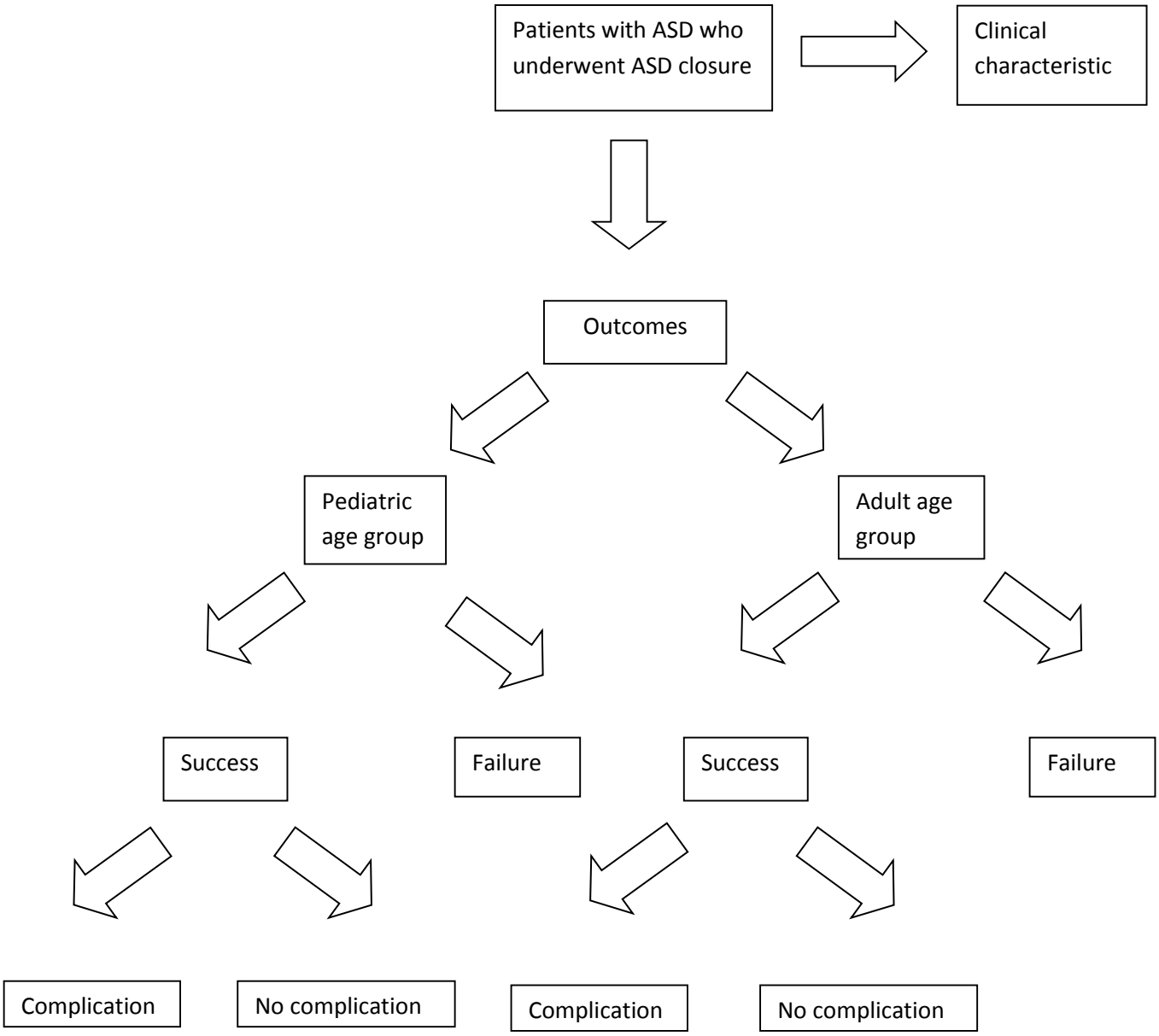
Mean ASDs diameter ranged from 10mm to 18mm in children (Baruteau *et al.,* 2014; O'Byrne *et al.,* 2014) while some centers performed closure for larger ASDs with mean ASDs diameter of 18.7mm (Kazmi et al). The ASDs diameter commonly increases with increasing age. The mean ASDs diameter ranged from 17.5mm to 28mm in adult (Baruteau et al, Huang et al).

Pulmonary artery mean pressure ranged from 17mmHg to 21.8mmHg (Oflaz *et al.,* 2013; Petit *et al.,* 2013; Saritas *et al.,* 2016). The pulmonary artery mean pressure in most of the studies were within normal range in all age group, due to the fact that patients with pulmonary hypertension were being referred to surgical team for surgical closure.

Many cardiac centers showed patients with very high success rate, as high as 98-100% (O'Byrne *et al.,* 2014; Saritas *et al.,* 2016). Some centers, however, had lower success rate (Oflaz *et al.*(2013) had only 56% for children and 64% for adult) and Vijarnsorn *et al.*(2012), a study from Thailand, with the success rate of 93%. Possible factors were developing countries, with minimum resources of pediatric cardiologists, intensivists and anaesthesiologists, trained staff, as well as minimum equipment available in their setting.

In terms of rate of complications, major complications ranges from 0.3% to 3.5% (Kazmi *et al.,* 2009; Vijarnsorn *et al.,* 2012) and minor complications ranges from 4% to 10% (O'Byrne *et al.,* 2014; Saritas *et al.,* 2016). Major complications were more common among adult, probably due to many underlying comorbidity. Minor complications were observed more among pediatric age group.

2.2.6 CONCEPTUAL FRAMEWORK



INDEPENDENT VARIABLES

DEMOGRAPHIC	CLINICAL CHARACTERISTIC	PROCEDURAL CHARACTERISTIC
1- Age on diagnosis 2- Age on procedure 3- Gender 4- Height 5- Weight 6- Comorbidity 7- Symptoms at day of procedure	1- ASD diameter 2- Pulmonary artery systolic & diastolic pressure 3- Pulmonary artery & left atrial mean pressure 4- Transpulmonary gradient 5- Qp:Qs ratio 6- Rim deficiency 7- Tricuspid regurgitation	1- Device size 2- Type or brand of device 3- Procedural time 4- Fluoroscopy time

2.2.7 METHODOLOGY

1. **Study design:** Retrospective record review.

2. **Study area:** This study was conducted in Hospital USM Kubang Kerian, Pediatric Cardiology Unit.

3. **Study duration:** The sample was collected from January 2005 until December 2015 (11 years).

4. **Study population**

    a. Reference population: Kelantan population with Atrial Septal Defects

    b. Source population: All cases visited HUSM for ASDs closure between January 2005 and December 2015

    c. Sampling frame: All cases visited HUSM for ASD closure between January 2005 and December 2015 that fulfills the following inclusion and exclusion criteria

5. **Study criteria:**

    a. Inclusion criteria: all patients that underwent ASD device closure in HUSM between January 2005 and December 2015.

    b. Exclusion criteria

        i. Association with other forms of congenital heart disease

        ii. Missed important information more than 30%

2.2.8 SAMPLE SIZE ESTIMATION

Sample size for first objective which was to describe demographic characteristics of the patients was determined using single proportion formula by sample size calculator (Version 2.0 Ariffin.W.N. 2017). Anticipated population proportion was 93%, according to rate of success from Vijarnsorn et al (2012). Precision was set as 5% with significance level of 0.050 and drop out of 10%. Sample size required to achieve this objective was 101 samples with corrected sample size of 113.

Sample size for second objective which was to determine media survival time to ASDs closure in adult and pediatric age group, was determined using PS Software version 3.0.10. Significance level was set at 0.05, with power of the study set at 80%. The median survival time was taken from Vijarnsorn et al (2012) which was 3 months, and median survival time set in our study was 1 year. Calculated sample size required from each group was 18 samples each.

Sample size for next objective, which was to compare the success rate between adult and pediatric age group in our center, was determined using PS Software version 3.0.10. Significance level was set at 0.05, power was set at 80%. The probability was set at 93%, according to success rate from Vijarnsorn et al (2010), and probability in our study was set at 97%. Sample size required to achieve this objective was 465 samples.

Sample size for the final objective, which was to compare the complications of ASDs closure between adult and pediatric age group, was determined using PS Software version 3.0.10. Significance level was set at 0.05, and power was set at 80%. The probability was set at 3%, referring to major complications occurred in a study by Behjati et al (2011), and probability in our study was set at 10%. Sample size required to achieve this objective was 194 samples.

Estimated number of sample between January 2005 and December 2015 are around 200. Thus we will take all patients within the study period.

2.2.9 SAMPLING METHOD AND SUBJECT RECRUITMENT

Sampling method was done by referring to the logbook containing all procedure done in invasive cardiac laboratory Hospital USM from January 2005 until December 2015. Patients with ASDs who underwent transcatheter device closure was extracted from the logbook, and the folder was traced from record office.

Data was collected from patients' folder and invasive cardiac laboratory report by using a standardized Case Report Form.

2.2.10 OPERATIONAL DEFINITION

Successful closure rate: The percentage of successful placement of device, with minimal or no residual shunt.

Residual shunt: The flow across the defect after device closure.

Failed closure rate: The percentage of failure to close the defect using device for reasons such as dislodged device, patient's deterioration on table and so on.

Abandoned procedure: Cases underwent device closure, but abandoned due to very large ASDs size, deficient rims, high pulmonary vascular resistance and so on.

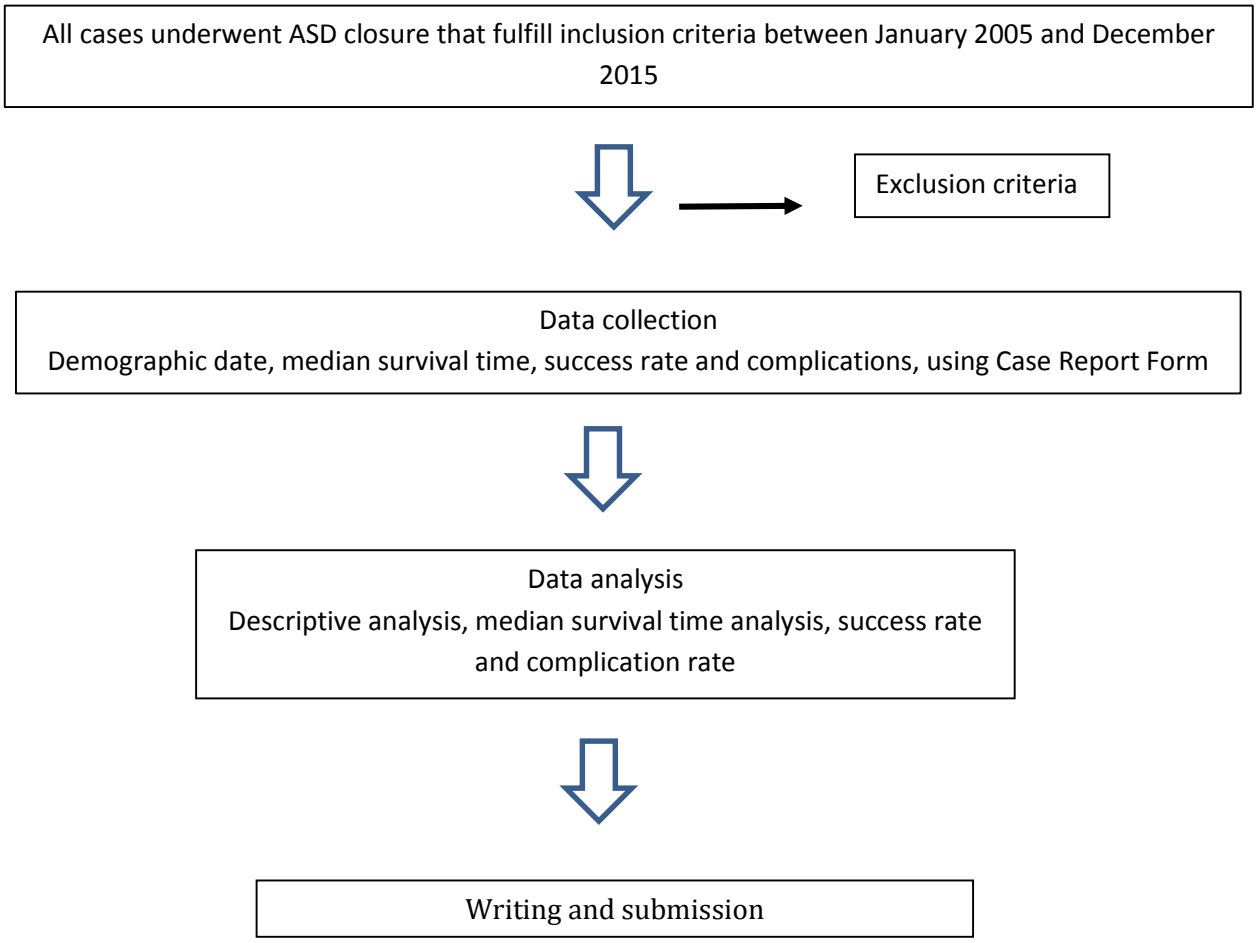
Major complications: Complications occurred during or after transcatheter device closure, which was life threatening and required urgent intervention, such as cardiac erosion, advanced AV block and atrial flutter requiring medications or pacemaker, thrombus formation that needed treatment with anticoagulant, cardiac tamponade causing hemodynamic instability that required urgent pericardiocentesis.

Minor complications: Complications occurred during or after transcatheter device closure, which resolved spontaneously without any intervention. Examples are trivial pericardial effusion that doesn't cause hemodynamic instability and resolved with time, local hematoma that resolved within few days with no compression effects, transient arrhythmia that resolved spontaneously without any medication.

Pediatric age group: Pediatric age group is 18 years old and below (according to WHO classification).

Adult age group: Adult age group is more than 18 years old (according to WHO classification).

2.2.11 STUDY FLOWCHART



2.2.12 DATA ANALYSIS

Data was entered and analyzed using SPSS software.

In primary objective, the first objective was to describe demographic and clinical characteristics of patients using descriptive analysis. Categorical data are presented as frequency (n) and percentage (%), while numerical data are presented as mean (SD) or median (range) based on their normality distribution.

The second objective was to determine the median survival time to close the ASDs in pediatric and adult age group. Kaplan-Meier Survival curve will be plotted – percentage of ASD closure done with time (in years).

In secondary objective, the comparison between success rate and complications in pediatric and adult age group. The data are evaluated using Chi Square Test or Fisher's Exact Test, and presented in cross-tabulation table.

2.2.13 EXPECTED RESULTS

TABLE 1: Descriptive data analysis of patients who underwent transcatheter ASDs device closure in HUSM

Categorical data	Total (n)	Pediatrics n(%)	Adult n(%)
Gender			
Comorbid			
-Genetic syndromes			
-Chronic diseases			
Symptoms			
Rim deficiency			
-Aortic rim deficiency			
-Anterior rim deficiency			
-Posterior rim deficiency			
Tricuspid regurgitation			

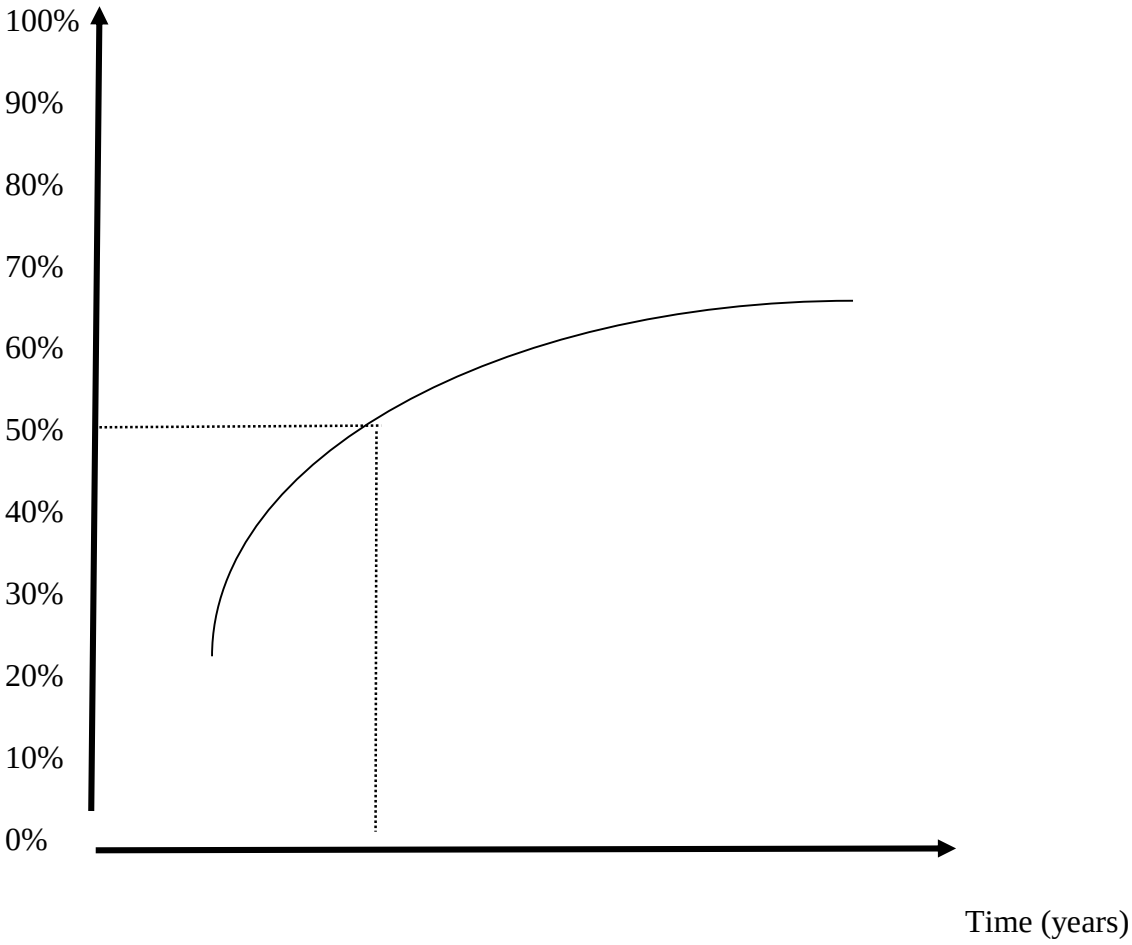
Numerical data

	Mean (SD)/Median (range)	Pediatrics	Adult
Age on diagnosis (years)			
Age on procedure (years)			
Weight (kg)			
Height (cm)			
ASD diameter (mm)			
Pulmonary artery pressure (mmHG)			
Transpulmonary gradient			
Qp:Qs ratio			
Device size (mm)			
Procedural time (min)			
Fluoroscopy time (min)			

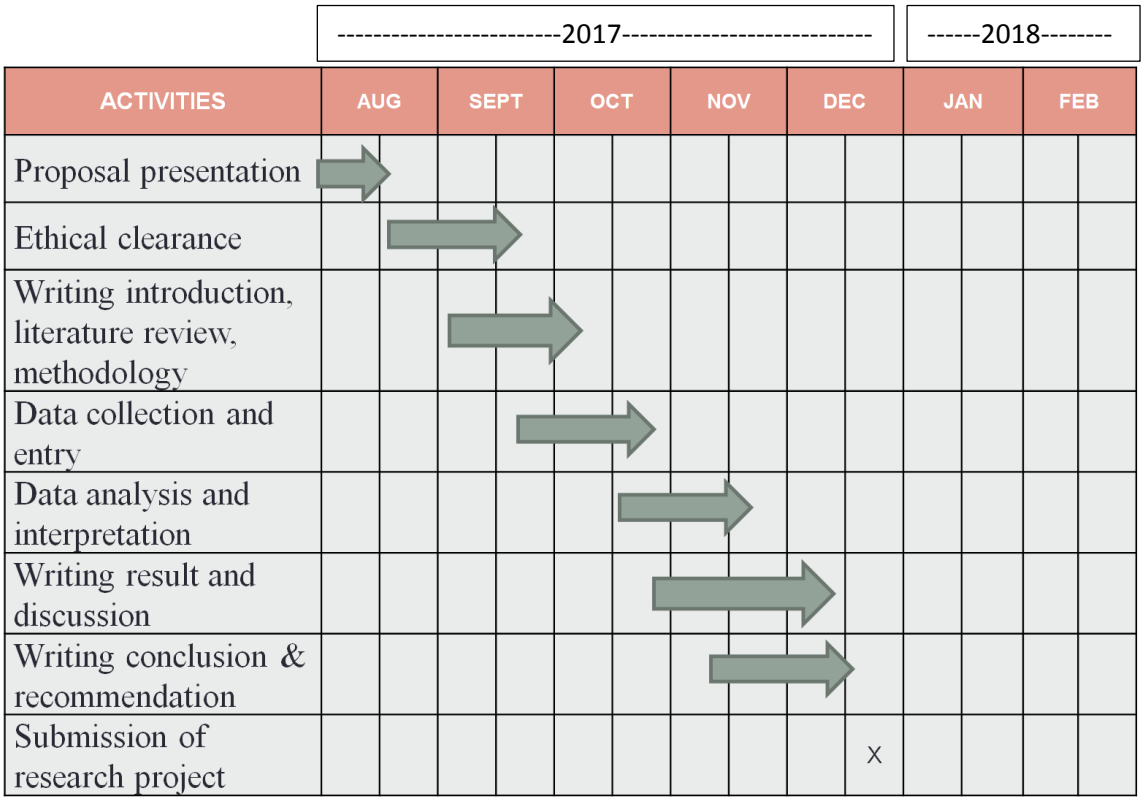
TABLE 2: Outcomes and complications of transcatheter ASDs device closure in HUSM

Demographic group	total (n)	Pediatrics n(%)	Adults n(%)	p value
successful closure				
residual shunt				
major complications				
-device embolization				
-cardiac erosion				
-advanced AV block				
-atrial flutter				
-thrombus formation				
-cerebrovascular accident				
-infective endocarditis				
-cardiac tamponade				
-death				
Minor complications				
-trivial pericardial effusion				
-aortic regurgitation				
-local hematoma				
-transient arrhtymia				
-migraine				

TABLE 3: Kaplan-Meier Survival curve on percentage of ASD closure (%) in pediatric/adult age group over time (years)



2.2.14 GANTT CHART & MILESTONE



2.2.15 ETHICAL CONSIDERATION

Data that were collected were a secondary data. Only data that were listed in Case Report Form were extracted out of patient's notes. Patients' identity will remain anonymous throughout the study. A separate list of names using code number were kept and only accessible by the primary investigator in a secure place. The researcher will not reveal any of the patients' name as a reference of any sort. All forms which are anonymous were entered into SPSS software. Data are presented as grouped data, and detail of patient will not be revealed.

The researcher does not have any conflict of interest in this study. The researcher also does not received any sponsor. Waive of consent was requested from Human Research Ethics Committee, HUSM, with letter of approval from the director of Hospital USM.

2.2.16 REFERENCE

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2.3 BODY CONTENT (MANUSCRIPT READY FOR SUBMISSION)

2.3.1 TITLE PAGE

OUTCOMES OF TRANSCATHETER DEVICE CLOSURE IN ATRIAL SEPTAL DEFECT SECUNDUM IN EAST COAST MALAYSIA : A SINGLE CENTER EXPERIENCE

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2.3.2 ABSTRACT

Transcatheter device closure of ASDs is commonly performed in pediatric and adult patients, and is a preferred method of closure. This study aims to describe demographic, procedural and clinical characteristic of our patients with ASDs who underwent the procedure, and its outcome in both age groups, and to look at median survival time to ASDs closure in our center. A retrospective study of 73 patients who underwent transcatheter ASDs device closure between January 2005 and December 2015 was performed in Hospital Universiti Sains Malaysia. Pediatric patients were 57.5% while adult patients were 42.5%, with 75% female predominance. The median age at diagnosis was 8 years old and median age at procedure was 15 years old. On procedural day, 25% of the patients were symptomatic, with reduced effort tolerance being the most reported symptoms. A majority of the patients had large ASDs, with a median of 22mm (7mm – 33.6mm), with 60% of the patients had rim deficiency. Success rate of device closure was 90.4%. There was 5.5% residual shunt immediately after procedure, with 100% complete resolution at the end of follow-up at 2 years. Median survival time of ASDs closure from the time of diagnosis in pediatric patients and adult patients were 3 years and 2 years respectively. ASDs device occlusion can be safely achieved in large ASDs population with rim deficiency, with comparable outcome and minimal serious complication.

Keywords – Atrial septal defect secundum, transcatheter device closure, rim deficiency

2.3.3 INTRODUCTION

Atrial septal defect (ASD) is one of the most common forms of congenital heart disease, with a prevalence of 10 to 20% of all congenital heart defects and incidence of one in every 1,000 to 1,500 live births [1,2]. Patients with ASD are usually diagnosed incidentally or present with symptoms such as easy fatigability, frequent lung infections and exercise intolerance. ASD secundum (ASDs) is the most common type of ASD. In a normal clinical course of ASDs, the highest number of spontaneous ASDs closure occur in patients younger than 2 years of age, especially patients with small ASDs (less than 5 mm) but rarely in moderate to large size ASDs [1-3]. The latter will remain either asymptomatic or develop symptoms along the way, and can complicate with pulmonary hypertension with increasing age [2,4].

ASD has been reported as early as the 1950s [5]. In the early years, surgical closure had been the method of choice and become the gold standard for the treatment of ASDs. Transcatheter method of ASDs closure was introduced in 1974, when it was first described by King et al [5]. Since then, a lot of advancements have been made in the use of catheters to close the ASDs. Extensive studies and reviews have been done in comparing the surgical method and transcatheter methods for ASDs closure. The latter has been the preferred method used worldwide [2,6,7].

Indications for transcatheter closure for ASDs include those with significant left-to-right shunt, with signs of right ventricular volume overload, regardless of symptoms [2,8]. Meanwhile, patients with irreversible pulmonary hypertension, patients deemed unsuitable for ASDs device closure on trans-esophageal echocardiography, very large ASDs diameter (more than 36mm) and