Immediate, Short and Intermediate Results of Transcatheter Closure of Secondum-Type Atrial Septal Defect Using Amplatzer Septal Occluder Devices

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Objectives: *To study the immediate, short, and intermediate results of transcatheter closure of secondum-type atrial septal defect using Amplatzer septal occluder devices (TCAA) in terms of clinical symptoms and residual lesions and shunts determined by transthoracic two-dimensional (TTE) and three-dimensional echocardiography (TDE).*

Material and Method: *Thirty-six patients, who underwent successful TCAA at the Chest Disease Institute between August 2002 and August 2007 and were followed up clinically, by TTE and TDE at day 1-3, 4-6 months, and 1-year post TCAA, were analyzed.*

Results: *TCAA was performed in 75 patients during the study period. Of these, 36 patients were completely followed-up. There were 92% female with a mean age of 40 $\pm$ 16 yrs (range19 to 65) and the mean of maximal size of ASD secondum determined by TTE, transesophageal echocardiography (TTE) and balloon sizing or balloon stretched diameter (BSD)was 18.9 $\pm$ 4.7 mm (range10-30), 22.6 $\pm$ 5.3 mm (rang10-32), and 24.3 $\pm$ 5.3 mm (range12-34) respectively. The size of ASOD was 26.4 $\pm$ 4.9 mm (range12-34).Fluoroscopic time was 16.4 $\pm$ 7.1 min (range 6.7-35.6). The success rate of TCAA was 84%. No major complications and deaths were found. All of those with successful TCAA apparently improved their functional class. All of them showed complete ASD closure and yet 12 (31%) had Qp/Qs $\geq$ 1.5 at year one.*

Conclusion: *TCAA is safe and effective and had resulted in clinical improvement, complete closure of secondum ASD, and good immediate, short, and intermediate outcomes with fewer complications.*

Keywords: *Secondum-type atrial septal defect (ASDII), Amplatzer septal occluder device (ASOD), Transthoracic echocardiography (TTE), Transesophageal echocardiography (TEE), Three dimensional echocardiography (TDE)*

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Transcatheter closure of secondum type atrial septal defect (ASD II) is an alternative treatment to surgical closure. Amplatzer septal occlude device (ASOD) was approved by United States Food and Drug Administration (US FDA) in December 2001 for ASD II in all ages. The condition for its applications are largest diameter of ASD II not greater than 34 mm, significant left to right shunt (Qp/Qs equal or more than 1.5), right ventricular volume overload and suitable anatomy especially adequate rims more than 5 mm for each[1]. Immediate, short, intermediate, and long-term outcomes post transcatheter closure of ASD II using Amplatzer ASD device (TCAA) were reported[2-6] using immediate hemodynamic data, clinical symptoms and two-dimensional echocardiography.However, there were a few reports of transthoracic two-dimensional echocardiography (TTE) simultaneously with real-time

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three-dimensional echocardiography (TDE) at immediate, short and intermediate post TCAA[7-10]. Therefore, the authors aim was to study the immediate, short, and intermediate results of TCAA in terms of clinical symptoms and residual lesions and shunts determined by TTE and real-time TDE.

Material and Method

Patients

Between August 2002 and August 2007, 75 patients with ASD II underwent TCAA at Chest Disease Institute. Subjects were patients aged 40 (range 19-65 years old) with ASD II who fulfilled the criteria for closure by an ASD occluder device (i.e. diameter of ASD $\leq$ 34 mm, Qp: Qs $\geq$ 1.5, adequate anatomical rim on the septum of attachment of device and RV enlargement). After successful TCAA, they were then followed at day 1-3, 1-3 months, 6 months, and 12 months with special emphasis on measurement by transthoracic two dimensions and three dimensions echocardiography (TTE and TDE). All patients gave consent.

The selection of the patients was done by using TTE and transesophageal echocardiography patients to evaluate the anatomical morphology and the maximal diameter of ASD II. The suitable patients for TCAA were the same as the above. The contraindications for TCAA were the associated congenital cardiac anomalies in which surgical correction was indicated, bleeding disorders, atrail fibrillation, any other contraindication for antiplatelets or heparin therapy, intracardiac clot on echocardiography (esp.LA or RA clot), in cooperation with TEE and the margin of the defects less than 5 mm to the coronary sinus, mitral valve, tricuspid valve, or right upper lobe pulmonary vein.

Amplatzer septal occlude device (ASOD) is constructed from a 0.004-0.0075 inches Nitinol (555 Nickel and 45% titanium) wire mesh that is tightly woven into two disks with a 3-4 millimeter connecting waist between the two disks (Fig. 1). The size of ASOD that is available in Thailand ranges from 12 to 34 mm. The waist of the ASOD is corresponding with the size but the left atrial (LA) disc and right atrial (RA) disc are 14 mm and 10 mm larger than the waist for ASOD size 12-34 mm. The central waist produces a radial force against the ASD rim, while the atrial disks flatten against the interatrial septum. The ASOD is self-expanding, self-centering, retractable, and repositionable. There are three Dacron polyester patches sewed with polyester thread into each disc and the connecting waist. These patches are designed for the purpose to facilitate thrombosis of ASOD post device deployment. There are two stainless steel sleeves with a female thread at the center of the RA disc, which is used to screw the delivery cable to the device. The size of the delivery system used for device deployment is ranging from 6F to 12 French. ASOD is connected to a delivery cable by a micro screw fixed to the RA disc and loaded into a 6-12 French long sheath. A balloon size catheter is a double-lumen balloon catheter with a 7F shaft and a compliant Nylon balloon. These catheters are available in two sizes: 24 mm and 34 mm. Balloon stretched diameter (BSD) has been regarded as a gold standard of measuring maximal ASD II size (Fig. 2). Typically, the optimal ASOD size is equal or 1-2 mm larger than the BSD.

TCAA protocol

Pre TCAA

1. Selection of the patients by physical examination, reviewing the TTE and TEE findings pre TCAA.

2. An informed written consent has been obtained from all.

3. Chest x ray (CXR), 12-lead electrocardiogram (ECG), complete blood count (CBC), blood chemistry (fasting blood sugar, renal function test), HBSAg, Anti HIV, PTT, and PT were performed in all.

4. ASA gr. V 1x1 & ticlopidine 250 mg bid or clopidogrel 75 mg bid 24 hours before procedure were administered.

5. Skin preparation at both groins and IV line was done.

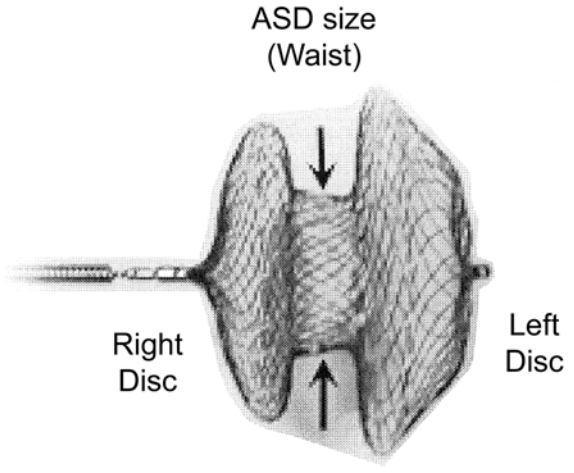

Fig. 1 Demonstrating the Amplatzer Septal Occluder device with the two discs and connecting waist

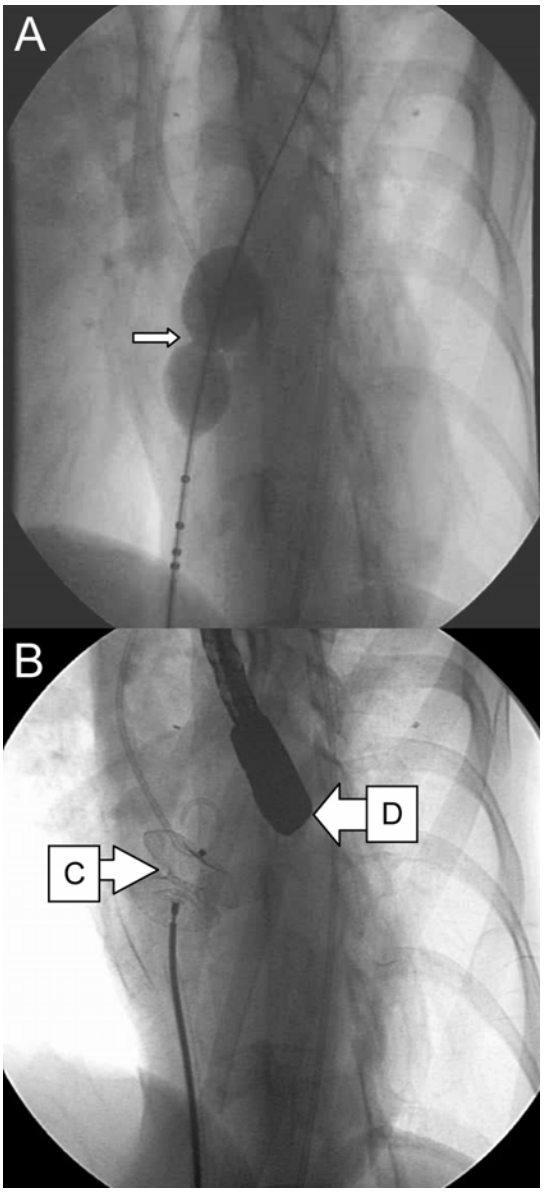

Fig. 2 Cine angiographic images at 50 degrees left anterior oblique and 20 degrees cranial in a patient with secondum type atrial septal defect. (2A) During balloon sizing of the atrial septal defect demonstrating the balloon stretched diameter (arrow). (2B) During placing the Amplatzer septal occlude device (C = ASOD)) and deployment the device under fluoroscopic and transesophageal echocardiographic (D = TEE) guidance

6. No antibiotics prophylaxis were given

7. Fasting or NPO at least 8 hours before TCAA procedure

TCAA procedure was done conventionally[2]

Post TCAA

1. Routine post cardiac catheterization care

2. TTE at D1 or D2 post TCAA is performed.

3. The medications given post TCAA are ASA gr. V 1 x 1 for 6 months, ticlopidine 250 mg bid or clopidrogrel 75 mg OD for 1 month, and analgesics.

4. Avoiding hard work for 1 month and infective endocarditis prophylaxis for 6 months is recommended.

5. For females, contraception for 1 year is recommended.

Follow-up protocol

• At 1-3 months, 6 months, and 1 year, TTE and TDE are performed to evaluate the residual ASD II, residual shunt (Qp/Qs), and the position of ASOD (Fig. 3).

• At 6 months and 1 year, CXR (PA and left lateral view) and ECG are performed.

Note. Transthoracic echocardiography was used to determine pulmonary systemic flow ratio or Qp/Qs[10].

Statistical analysis

The data were expressed as mean $\pm$ SD and ranges as appropriate. Nominal variables were compared by Fisher's extract tests; continuous variables were analyzed by ANOVA with repeated measurement and 2-sided, paired t-tests. $p < 0.05$ was considered statistically significant.

Definition

- Complete closure of ASD or no residual AD means that there is no residual ASD determined by transthoracic echocardiography with color flow across interatrial septum.

- Residual shunt means that pulmonary systemic flow ratio or Qp/Qs is equal or more than 1.5.

Results

The results showed that out of 75 patients, 63 (84%) were successfully occluded and 36 could be followed as scheduled. There was one patient with two ASD II that was closed by a single device covering two defects.

There were 92% female with mean age of 40 $\pm$ 16 years (range19 to 65), 70% New York Heart Association (NYHA) function class 2, and the mean of maximal size of ASD secondum determined by TTE, transesophageal echocardiography (TTE) and balloon

sizing was 18.9 ± 4.7mm (range10-30), 22.6 ± 5.3 mm (range10-32), and 24.3 ± 5.3 mm (range 12-34.) respectively. The mean size of ASOD was 26.4 ± 4.9 mm (range12-34). Mean pulmonary artery pressure was declined from 36.3 ± 16.4 mmHg (range 21-61) to 25.9 ± 3.9 mmHg (range16.8-33). One patient with large ASD II and large ASOD (device diameter of 34 mm) had transient sinus bradycardia post TCAA but it returned to normal at 48 hours post TCAA. There was one complication of device embolization occurring in a young female patient with a 24 mm ASOD that appeared to be stable at the time of implantation but embolised to right pulmonary artery detected by TTE and fluoroscopic 24 hours post TCAA. Then, the device was retrieved by a cardiothoracic surgeon and surgical ASD II closures were performed at the same time without any further complications. Fluoroscopic time was 16.4 ± 7.1 min (range6.7-35.6). No other major complications and deaths were found. All patients were discharged from the hospital within 48 hours post TCAA.

Follow up evaluation revealed that all apparently improved their functional class. TCAA 1-3 days, TTE and TDE showed complete closure of ASD in all except two with small residual ASD and at 6-12 months, all has no residual ASD. The absolute changes of PAP at 3 months, 6 months, and 12 months were -10.7 ± 9.1 mmHg, -13.23 ± 12.51 mmHg, and -14.1 ± 9.7 mmHg, respectively. The mean pulmonary artery pressure (PAP) was significantly reduced from pre TCAA; 36.3 ± 16.4 mmHg (range 21-61) to 22.6 ± 6.7 mmHg (range 16-32) post TCAA at 1 year ($p < 0.001$) (Table 1). The absolute changes of the main pulmonary artery size at 3 months, 6 months, and 12 months were -1.16 mm, -2.25 mm, and -1.9 mm, respectively. The mean size of the pulmonary artery did not change significantly from pre TCAA; 27.1 ± 4.1 mm (range 20-35) to 25.1 ± 4.2 mmHg (range 16-33) post TCAA at 1 year ($p = 0.07$) (Table 1). The absolute changes of the left to right shunt or Qp/Qs at 3 months, 6 months, and 12 months were -2.11 ± 1.51, -2.22 ± 1.72, and -2.03 ± 1.23, respectively. The mean Qp/Qs was significantly reduced from pre TCAA of 3.52 ± 1.96 to post TCAA at 1 year of 1.5 ± 0.27; ($p < 0.0001$) (Table 1). However, the residual shunt flow or Qp/Qs more than or equal 1.5 is shown in 28 patients (72%), 12 patients (31%), and 12 patients (31%) at day 1-3, 4-6 months, and 12 months, respectively.

Table 1. Comparison between the size of main pulmonary artery, mean pulmonary artery pressure and pulmonary-systemic flow ratio (Qp/Qs) before transcatheter closure of secondum type atrial septal defect using Amplatzer septal occlude devices (TCAA) and 1 year after the procedure

Parameters	Before TCAA	1 year after TCAA	p-value
PA size (mm)	27.1 ± 4.1	25.1 ± 4.2	0.07
PAP (mmHg)	36.3 ± 16.5	22.6 ± 6.7	<0.001
Qp/Qs	3.5 ± 1.9	1.5 ± 0.7	<0.001

Discussion

The prevalence of ASD II was approximately 10% of congenital heart disease at birth and as much as 30-40% in adults with congenital heart disease. Transcatheter or percutaneous closure of ASD II is an alternative to surgical treatment and the first report of this treatment in humans was published in 1976 by King and Mills[12,13]. The ASOD is a favorite and preferable choice among the other devices; ASOD, Cardio SEAL, Cardio SEAL-STAR Flex Septal Occulder, PFO gold star and Helex Septal Occluder[14-16]. Advantages of the ASOD include a smaller delivery sheath and greater ease of retrieval before release of the device, reducing the likelihood of tissue damage I[5]. In most of the more recent studies with ASOD, the success rate of implantation is more than 90%[17,18] but in the presented data, the success rate was 84%. In details, the present study had the learning curve in the first 25 cases. In some reports, the success rate was 79.4%[6] and 84.7%[4].

TCAA is not only an effective procedure but also a safe one. The complications related to the procedures are significantly lower for TCAA when compared to surgical closure (7.2% vs. 24%)[17,19]. No deaths and serious complications were reported in the present study except one with device embolization. The cause of this complication may be from the undersize of ASOD and there were some reports of delayed ASOD embolization occurring at 1-week post TCAA[20]. Transient bradycardia was experienced in one case in the present study. Arrhythmias such as supraventricular tachycardia and ventricular arrhythmia were reported immediately and 24-hours post TCAA[21,22]. Improvement of NYHA functional class was found in all, which was comparable to other studies[17-20].

Numerous reports revealed the role of transesophageal echocardiography (TEE), transthoracic TDE, transesophageal TDE, and intracardiac echocardiography (ICE) before and during TCAA procedures[9,27]. Before TCAA, the accurate size of ASD II was assessed by using TEE and TEE TDE compared

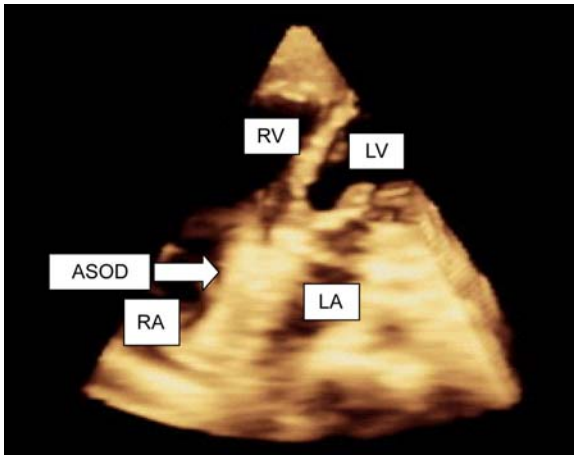

Fig. 3 Three dimensional echocardiography, 24 hours post transcatheter closure of secondum type ASD demonstrating the Amplatzer septal occluder in place and no residual ASD (RA = right atrium, RV = right ventricle, LA = left atrium, LV = left ventricle, ASOD = Amplatzer septal occluder device)

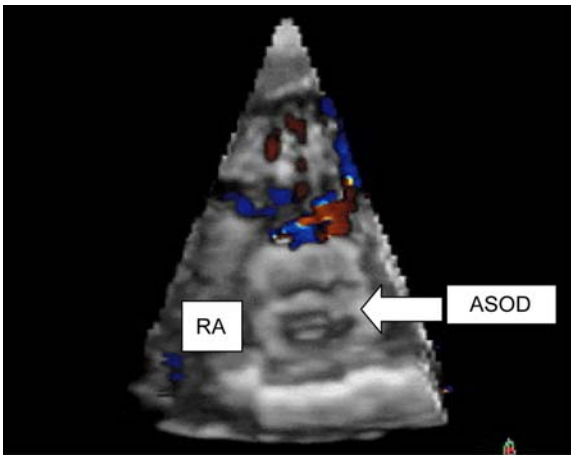

Fig. 4 Three dimensional echocardiography, I year post transcatheter closure of secondum type ASD demonstrating the Amplatzer septal occluder in place from the right atrial site like "figure of 8" (RA = right atrium, ASOD = Amplatzer septal occluder device)

with the balloon stretch diameter. TDE demonstrated the oval shape, the size, and the site of ASD II[9,24,26,27]. TDE provides the details of the morphology of the heart in the quality of intraoperative findings[28]. TDE allows the unique en face views of the ASD II and ASOD from either left atrial site or right atrial site (Fig. 3, 4) and has the ability to measure the maximal diameter and the area of the ASD II and ASOD in systolic and diastolic phase[29]. Meanwhile, two dimensional echocardiography cannot display the diastolic-systolic difference of the ASD II.TDE provides the actual shape of ASD II and ASOD[30], the angle of the ASD axis and allows cross sectional imaging in any acquired planes. From the right atrial site, TDE showed the feature of ASOD like "figure of 8", which was first described in this present study (Fig. 4).

Immediate results of TCAA revealed complete closure of ASD II at the following days post TCAA demonstrated by TTE and TDE with color flow in 34 patients (89.5%). In another study, the closure rate at 1-day pot TCAA was 91.3%[6]. By using TTE and TDE, the authors found that at 4-6 months, only one patient had small residual ASD and complete closure in all at 1 year. Other studies also reported that complete closure was found at 2.3 years[4] and 3 years[6].

Residual shunt flow determined by Qp/Qs equal or more than1.5 was found in 31% post TCAA at 6 months and one year. It is because the size of RVOT and pulmonary artery had not reduced to normal post TCAA even when there was no color flow across the inter arterial septum.

Conclusion

TCAA is safe and effective and has resulted in clinical improvement, complete closure of secondum ASD with fewer complications.

Acknowledgement

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ผลการรักษาผนังกั้นหัวใจด้านบนรั่วโดยผ่านทางสายสวนและใช้อุปกรณ์ amplatzer ASD occluder deviceในระยะเฉียบพลัน ระยะสั้นและระยะปานกลาง

เกรียงไกร เฮงรัศมี, พีรพัฒน์ เกตุค้างพลู, พรวลี ปรปักษ์ขาม, วทัญญู ปลายเนตร, เอนก กนกศิลป์, จรินทร์ อัศวหาญฤทธิ์, บุญจง แซ่จึง

วัตถุประสงค์*: เพื่อศึกษาผลการรักษา การปิดผนังกั้นหัวใจด้านบนที่รั่ว โดยผ่านสายสวนและการใช้อุปกรณ์พิเศษ amplatzer ASD occluder device ทั้งระยะเฉียบพลัน (1-3 วัน) ระยะสั้น (4-6 เดือน) และระยะปานกลาง (1 ปี) โดยประเมินจากอาการทางคลินิกและผลการตรวจหัวใจด้วยคลื่นเสียงสะท้อนความถี่สูง*

วัสดุและวิธีการ*: ตั้งแต่สิงหาคม พ.ศ. 2545ถึงสิงหาคม พ.ศ. 2550 สถาบันโรคทรวงอกได้ปิดผนังกั้นหัวใจด้านบนที่รั่วโดยผ่านสายสวน และการใช้อุปกรณ์พิเศษ amplatzer ASD occluder device (ASOD) เป็นจำนวน 75 ราย อัตราความสำเร็จ 84% ได้คัดเลือกผู้ป่วยเข้าในการศึกษาจำนวน 36 รายซึ่งเป็นรายที่ได้รับการประเมินจากอาการทางคลินิก และผลการตรวจหัวใจด้วยคลื่นเสียงสะท้อนความถี่สูงครบถ้วนทั้ง 3 ระยะเวลา*

ผลการศึกษา*: ในผู้ป่วย 36 รายส่วนใหญ่เป็นผู้หญิง (92%) อายุเฉลี่ย 40 $\pm$ 16 ปี (พิสัย 19-65) ขนาดของ ASD secondum ประเมินจากการตรวจหัวใจด้วยคลื่นเสียงสะท้อนความถี่สูงผ่านทางหน้าอก การตรวจหัวใจด้วยคลื่นเสียงสะท้อนความถี่สูงผ่านทางหลอดอาหารและวัดโดยการใช้บอลลูน ชนิดพิเศษมีค่า เท่ากับ 18.9 $\pm$ 4.7 มิลลิเมตร (พิสัย 10-30), 22.6 $\pm$ 5.3 มม. (พิสัย 10-32) และ 24.3 $\pm$ 5.3 มม. (พิสัย 12-34) ตามลำดับ ขนาดของอุปกรณ์ ASOD ที่ใช้เฉลี่ยขนาด 26.4 $\pm$ 4.9 มม. (พิสัย 12-34) สำหรับ fluoroscopic time เท่ากับ 16.4 $\pm$ 7.1 นาที (พิสัย 6.7-35.6) ผลการรักษาพบว่า ผู้ป่วยทุกรายมีอาการทางคลินิกดีขึ้น กล่าวคือเหนื่อยน้อยลงและไม่มีผลแทรกซ้อนที่รุนแรง มีผู้ป่วย 2 รายที่มีรอยรั่วของ ASD ขนาดเล็ก ๆ เหลืออยู่ และเมื่อตรวจติดตามด้วย Echo พบว่าหายไปในระยะเวลา 6-12 เดือน ผลการตรวจ Echo ในระยะเฉียบพลัน ระยะสั้นและระยะกลาง พบว่ามี Qp/Qs มากกว่าหรือเท่ากับ 1.5 เป็นจำนวน 28 ราย (72%), 12 ราย (31%) และ 12 ราย (31%) ตามลำดับ*

สรุป*: การปิดผนังกั้นหัวใจด้านบนที่รั่ว โดยผ่านสายสวนและการใช้อุปกรณ์พิเศษ amplatzer ASD occluder device มีความปลอดภัยและได้ผลดีทั้งทางด้านคลินิก และผลการตรวจ Echo โดยที่ไม่มีผลแทรกซ้อนที่รุนแรง ทั้งในระยะเฉียบพลัน ระยะสั้น และระยะปานกลาง*