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COMPARISON OF STABILITY AND STERNUM HEALING RATE IN CLINICAL AND ULTRASONOGRAPHY (USG) BETWEEN STAINLESS STEEL WIRE AND POLYDIOXANONE YARN IN CHILDREN HEART SURGERY OPERATION

(Running Head: Stability and Healing Rate of the Internet and Ultrasonograph)

[1]Prima Kharisma Hayuningrat, [2]Paulus Rahardjo, [*3]Heroe Soebroto

Abstract---Background: The closing of the sternum bone is often used today by using stainless steel wire material and Polydioxanone yarn continuous suture. To objectives to be achieved for sternal healing after heart surgery without complications resulting from the failure of sternal healing. The bone healing process itself is influenced by mechanical stress and movement.

Objectives: To compare the effects of sternum closure techniques on surgical patients The heart of the child uses Polydioxanone and Stainless Steel Wire threads against clinical stability and rate of healing which are evaluated clinically and Ultrasonography.

Methods: Performed sternal closure of pediatric patients after cardiac surgery with sternal wire (n = 8) and PDS (n = 8). Performed sternal pain and stability evaluation with the physical examination. Further sternum ultrasonographyund was performed to assess displacement, gap and callus picture. Evaluations were performed at weeks 6, 9 and 12 postoperatively.

Results: Week 6 and 9 degrees of pain were higher in sternal wire compared with polydioxanone (p = 0.03 and p = 0.01). The 12th week of sternal wire and polydioxanone did not find any difference in pain (p = 1,000). Week 6, 9 and 12 there was no clinical stability difference between wire and PDS (p = 0.143, p = 0.264, p = 0.063). 9th, 9th and 12th Sternum ultrasonography of examination appears to be displacement in polydioxanone (p = 0.025, p = 0.009, p = 0.009). The gap increased significantly from 6th to 9th weeks in the polydioxanone group, while the addition at week

[1] ***Prima Kharisma Hayuningrat[1],***
[1]Thoracic Surgery, Cardiovascular and Vascular, Faculty of Medicine, Universitas Airlangga, Surabaya 60131, Indonesia
+62315020251, info@fk.unair.ac.id
[2]Paulus Rahardjo
[2]Department of Radiology, Faculty of Medicine, Universitas Airlangga (60131), Indonesia
Phone: +62315020251, info@fk.unair.ac.id
Corresponding Author: [3]Heroe Soebroto
Corresponding author's Address: Department of Thoracic Surgery, Cardiovascular and Vascular, Faculty of Medicine, Universitas Airlangga (60131), Indonesia
Phone: +62315020251, info@fk.unair.ac.id
E-mail : unairsubroto@gmail.com

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9 to 12 was statistically insignificant but it appears that polydioxanone had a wider gap addition range than the sternal wire. Week 9 and 12 callus were seen more often in sternal wire patients but not significant (P = 0.602, p = 0.333)

Conclusion: Clinically, sternal steal wire stability is proportional to polydioxanone. Radiologically, the stability of sternal wire is better than polydioxanone. The rate of sternal cure in polydioxanone is proportional to the sternal wire.

Keywords--- *Sternal wire, Polydioxanone, Sternum ultrasonography, Paediatrics*

I. INTRODUCTION

Sternotomy was first introduced in 1897 by using experimental goats and human cadaver which then succeeded, then in 1957, performed sternotomy action on heart surgery patients(1, 2). In the USA, more than 750.000 median sternotomy procedures are performed annually for cardiac surgery(3).

Today, closure of the sternum bone that is often used by using stainless steel wire material (SS). The commonly used closure techniques are figure-of-8 and simple interrupted techniques. Biomechanical studies on cadavers and animals show the efficacy of several sternal closure techniques with different results(4-6).Currently, the use of synthetic polydioxanone absorbable suture after sternotomy becomes a routine procedure performed in many heart surgery centers, especially in cases of heart surgery in pediatric patients. Several studies have shown the use of polydioxanone (PDS) is effective in preventing sternal instability, assisting wound healing and is more suitable for pediatric patients(7, 8).In addition, the PDS handling is easier to use, lowering the risk of bleeding at the stitching site and reducing postoperative pain(9-11).

The use of PDS in cardiovascular surgery was first performed on the sternum closure procedure for various heart operations such as correction of coarctation of the aorta, total correction Pulmonary vein drainage anomaly, arterial switches in Transposition of Great Arteries and systemic pulmonary shunts. Postoperative results obtained polydioxanone does not cause inflammatory and mediastinitis reactions, at least granulation tissue and is well-absorbed within the span of 2-6 months. The strength of fixation on the sternum is influenced by the type of fixation technique, the amount, strength and thickness of the wire used and the strength of the sternum itself(12, 13).

The main goal to be achieved from the sternum closure technique is the achievement of sternal healing after heart surgery without any complications due to sternal healing failure. There are two important factors in bone healing process including mechanical stress and movement which can affect sternum technique stability in callus formation process, the formation or gap between the two sides of the split sternum and the fixation of movement between the sternal fragments(14, 15).

The routine procedure performed in Dr.Soetomo General Hospital in sternal closure after childhood heart surgery is the most frequent use of continuous suture Polydioxanone yarn while the SSW of the figure of eight is rarely used. Evaluations to assess sternal healing include clinical evaluation of pain scale and physical examination scale assessing sternal stability using the scale.(16).This evaluation was used in several studies of sternal stability assessment after adult heart surgery(17)But there has not been much study in patients after child's heart surgery.

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Radiological evaluation of sternal healing can be used as a modality chest x-ray by assessing the presence of midsternal sign radiolucent image on the sternum indicating sternum healing failure(10), but the sternal picture in pediatric patients can not be well visualized compared to adult cardiac surgery patients. The modalities that can be used to assess sternal morphology are by ultrasonography (ultrasonography)(18, 19). Studies performed using sternal ultragraphyin patients with sternal instability post adult heart surgery can be concluded that sternum ultrasonography has good reliability to assess sternal healing post-sternotomy in adult cardiac surgery patients by assessing abnormal movements and gaps in the sternal midline post-sternotomy(17).

Based on, the study literature comparing the two uses of this material to a child's heart surgical patient as well as evaluating the ratio of its cure. Until now, no research results have been found, therefore, this study intends to compare the effect of sternum closure technique on the patient's heart surgical patients using Polydioxanone and Stainless Steel Wire threads on clinical stability and rate of healing which is evaluated clinically and Ultrasonography.

II. METHODS

This study used a double-blinded randomized clinical trial design in patients with cardiac surgery performed by the sternal closure. The study was conducted in the operating room of cardiac surgery, radiology ultrasonography examination room and polyclinic surgery of Toraks, Kardiak, and Vascular Dr.Soetomo General Hospital, Surabaya. The study was conducted from 2016 to 2017. The inclusion criteria included pediatric patients undergoing open and closed heart surgery with a 1-10-year-old sternotomy approach with 10-20 kg. Redo surgery, re-surgery due to postoperative hemorrhage and the patient dies or did not control during the observation period of the study was excluded.

The research procedure, covering the selection phase of the patient according to the inclusion criteria, then the research tool needed sternum closure technique using two types of material include Stainless steel wire and polydioxanone synthetic yarn. Furthermore, in the treatment stage, all patients undergoing standardized cardiac surgery procedures adhere to diagnose and prevailing protocols. In this research use routine stitching technique done at Dr.soetomo Hospital that was continuous suture and figures of-8. The suturing process will use at least 3 SS wire fixations with the figure of -8 and 6 continuous stitching Polydioxanone for each sternum. Furthermore, the observational stage of the study, the patient was evaluated postoperatively with evaluation at the cardiac surgical polyclinic at 9th, 12th week. The device used in the evaluation consisted of a clinical examination of pain, a physical examination on the sternum to assess stability was performed using the modified sternal instability scale method; sternum ultrasound examination with the transversal projection at three checkpoints (upper sternum, mid sternum, and lower sternum).Statistical data processing by using Mann Whitney Test for the non-parametric test with SPSS v23 program (SPSS, Inc., Chicago, IL.).

III. RESULTS

Clinically observed stability parameters are the degree of pain and sternal suppression stability with clinical examination and evaluation of displacement of ultrasound. While the parameters of sternal healing rates observed radiologically are sternum discontinuities (gaps), and bone unification processes assessed from the callus image.

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The first group of sternal bone was fixed with sternal wire with the stitch of the figure of eight and the second group was fixed with PDS with simple continuous stitching. Patients were followed for postoperative physical and radiological examination at weeks 6, 9 and 12. The sternal closure images with PDS and sternal wire bias are seen in Figures 1 and 2.

Characteristics of the study

This study was performed on patients undergoing a child's cardiac surgery procedure via sternal access sternal. The sample selection procedure was performed randomly with a weight range of 10-20 kg. The mean weight gain was 12.43 ± 3.150 kg in sternal wire and 12.13 ± 3.064 in PDS with age range of 8.90 ± 1.560 years and 8.60 ± 1.320 years respectively. The procedure includes all open or closed heart surgery procedures which are the first surgery instead of a redo surgery.

Comparison of Stability Test Results

The results of stability were obtained in the 6th-week evaluation results in patients using sternal wire, showed a higher degree of pain compared with PDS ($p = 0.03$) with sternal wire group pain characteristics in mild to moderate to severe degrees. While in the PDS group all patients felt a mild degree of pain. Evaluation at week 9 of patients using sternal wire still showed the higher degree of pain than PDS ($p = 0.01$) but with lower pain level characteristics. All patients with sternal wire experience mild pain up to moderate pain level, whereas in PDS half of patients have no pain. In the 12th week, both sternal wire and PDS were not found significant differences in pain ($p = 1.000$).

On clinical examination, no significant stability difference was obtained at week 6 between the sternal wire and PDS ($p = 0.143$). In the 9th week, there was also no significant stability difference between sternal wire and PDS ($p = 0.264$). At week 12 there was no statistically significant difference in stability between the 2 groups ($p = 0.063$).

At the 6th-week ultrasound examination, the use of PDS showed a significant displacement compared to the use of sternal wire ($p = 0.025$). At 9th week ultrasound evaluation still showed significant displacement compared to sternal wire ($p = 0.009$) and at week 12 evaluation PDS still showed a significant displacement compared to sternal wire ($p = 0.009$) but no new displacement at other patients.

Comparison of Results Healing Rate

The results In the sixth week USG examination found a significant gap difference which obtained a wider gap in PDS in Manubrium ($p = 0.021$) while at mid and lowers there was no significant gap difference ($p = 0.094$ and $p = 0.728$). On the ultrasound examination also has not obtained any callus picture either in the PDS group or sternal wire.

In the 9th-week gap assessment, there was a significant difference with the wider gap of PDS in Manubrium sternum ($p = 0.005$) and on the sternum Corp ($p = 0.001$) while on the lower sternum there was no significant gap difference ($p = 0.069$). In the 12th week, there was a significant difference with the wider gap in the PDS group, i.e., in the Manubrium sternum ($p = 0.001$), the sternum Corp ($p = 0.002$) and the lower sternum ($p = 0.029$).

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When compared to the number of gap additions at the 6th, 9th, and 12th-week checks, the gap size increased significantly from week 6 to 9 in the PDS group compared to the sternal wire group. The addition of a gap occurs at all points of the sternal examination. The addition of the gap at the 9th to the 12th week was not statistically significant but it appears that PDS has a wider gap addition range than the sternal wire.

In this 9th week, we have got callus picture on PDS group and sternal wire. The number of patients seen callus in the sternal wire group was more than the PDS, but not statistically significant compared to the PDS group (P = 0.602). In the 12th week of ultrasonography results, there was a callus profile of both the PDS and the sternal wire with more callus numbers obtained in sternal wire patients but not statistically significant (p = 0.333).

IV. DISCUSSION

The stability and healing of the sternum in this study was stability and clinical and radiological healing evaluation at 6th week, 9th week and 12th week. The sternal stability was evaluated based on the degree of pain on clinical examination as well as the physical examination to assess sternal stability and then evaluate the presence or absence of displacement by examining ultrasonography. While the healing of the sternum was assessed through ultrasonography examination based on the evaluation of the gap on the sternum as well as the callus picture on the sternal fragment.

Examination to assess the degree of pain was performed in the outpatient unit with emphasis on the sternum then assessed the patient's pain response according to the scale by age group. At the 6th-week evaluation physical examination, the degree of pain appeared to be higher in the sternal wire group than in the PDS group. This was in accordance with the study on(11)polydioxanone pediatric patients have a low level of pain because the PDS did not cause an inflammatory reaction with minimal granulation tissue.

The evaluation of 9th week showed that the pain scale was still higher in sternal wire compared to PDS (p = 0.01) but more decreased compared with week 6 evaluation. Although at the beginning of the evaluation of pain the use of PDS was more convenient for pediatric patients than in sternal wire the results of the 12th week of all groups showed no significant pain relation. This was likely due to an already running healing process.

Pain examination was performed simultaneously by assessing stability of the sternum and assessed on a scale(16).In the PDS group, three patients with minimal sternal instability were statistically examined at 6th, 9th and 12th weeks. There was no significant difference between PDS and sternal wire. The pain in this patient was related to the characteristics of the sternum closure technique and its interaction with the surrounding tissue not due to the effects of sternal instability. The stability and healing process of the sternum is influenced by the combination of daily physiological movements such as breathing, coughing and moving that create a force on the sternum. The force was the result of a combination of transverse shear, longitudinal shear, and lateral distraction movements. In this study at weeks 6, 9 and 12 seen in ultrasound there was a significant displacement in the PDS group. This study was in accordance with the study wherein the Sternal wire group with strong material properties, proved to have a much better rigidity(20)compared to PDS and this was indicated by a stable symmetry of the sternum.

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At week 6 there was a wider gap in the Manubrium and Corpus Sternum groups of PDS than in Sternal wire. The gap differences remained significantly larger at the 9th and 12th weeks. This difference is due to the fact that the PDS uses absorbable material which will certainly be degraded over a period of time. Based on the PDS profile of ethicon® the power of the PDS at week 2 will decrease to 70% and will decrease gradually to 25% at 6th week(21). The addition of a gap at the 6th, 9th, 12th USG evaluation shows the PDS is not as strong as Sternal wire in maintaining the sternum position. the strength of Sternal wire material derived from stainless steel metals makes it able to fix the sternum well so there was no displacement or widening gap. In addition, as in the study, the biomechanical properties of sternal wire are able to provide better rigidity so as to withstand the effects of physiological movements of patients such as coughing, breathing or daily activities, resulting in a smaller stretch compared to PDS(20).

At the end of the 12th week of study, the PDS gap compared to the sternal wire was 19.25 ± 1.83 vs 13.75 ± 1.58. This shows the evaluation of PDS usage by ultrasonography is seen widening and addition of bigger gap than sternal wire. Although the use of Sternal wire proves to be more confined in fixing the Sternum, PDS threads were also able to maintain the gap of Sternum with a distance below 2 mm can trigger the running of the healing process (fibrous tissue healing). Based on this research, there was a displacement in PDS and the larger gap with increasing trend compared to sternal wire. The sternal wire has better stability than PDS. However, on the evaluation of callus formation at 6 weeks by ultrasound has not seen any callus between the two. By the 9th week, the callus looks already in the PDS group and the sternal wire. Callus formed in the sternal wire group was higher than PDS (4 patients vs 2 patients) but was not statistically significant. At week 12 the callus was seen increasing the number in the two groups (PDS 5 vs sternal wire 4) but not statistically significant.

Although the calculation of statistics was not significant but appears in the group sternal wire the formation of callus occurs earlier than PDS. The presence of displacement did not significantly affect the formation of callus during the gap that occurs still in the range of less than 2 mm distance. Thus the results of this study were appropriate that there was a correlation between gap distance with bone unification process and with a gap of less than 2 mm both PDS and sternal wire can achieve optimal healing(15). Although in PDS evaluation a little late in terms of healing compared with sternal wire at the end of the study, it appears the healing process between the two was comparable. The lateness of the PDS healing process was probably due to the physiological movement of the sternum causing a shift in the PDS so that theoretically would interfere with healing even though the level of shift within the limits was still tolerable and this evidenced by the formation of callus. Technical rigidity will affect sternal stability so that it will affect the healing process.

Overall end-of-study results at 12 weeks showed Sternal wire and PDS clinically had comparable stability but from ultrasound examination, sternal wire showed better stability as indicated by symmetric sternal position than in the PDS group that significantly showed a displacement. While the evaluation of the healing rate at the end of the study (week 12) showed that the sternum gap was significantly greater in PDS than the sternal wire but statistically the callus seen on the sternal wire and PDS showed no significant difference. Thus statistically the sternal wire group did not show a faster healing process than in the PDS group. In this study, it appears that ultrasound has the advantage to evaluate sternal stability and healing in terms of ease, safety, and cost that is relatively affordable compared to CT-

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Scan which was a gold standard to see the condition of the sternum. During the study, there was no sternal or chronic pain, but one patient with a sternal wire sternum detected an abscess over the bone of manubrium.

Sternal wire causes higher pain than PDS. Clinically, sternal wire stability was proportional to PDS. Radiologically, the stability of sternal wire was better than PDS. PDS produces a wider sternal gap than a sternal wire. The rate of sternal healing in the PDS was proportional to the sternal wire.

ETHICAL CLEARANCE

This study has been approved ethically by the Research Ethics Committee Dr.Soetomo General Hospital based on the certificate of ethical worthy of number 678/Penke.KKE/XI/2016

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This manuscript has been published in the repository of the University Airlangga library in 2017 linked to the website as follows (http://repository.unair.ac.id/65688/) with the title, "Comparison Of Stability And Sternum Healing Rate In Clinical And Ultrasonography (Usg) Between Stainless Steel Wire And Polydioxanone Yarn In Children Heart Surgery Operation.

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TABLES

Table 1: Characteristics of the patients

	Sternal wire		PDS	
Sex	Male	Female	Male	Female
	6	2	5	3
Weight (kg)	Mean		Mean	
10 – 20	12.43 ± 3.150		12.13 ± 3.064	
Age(y/o) 0 – 12	8.90 ± 1.560		8.60 ± 1.320	

Table 2: Procedure operation

Procedure	Frequency	Percentase
ASD Closure	4	25.0
BCPS	2	12.5
BT Shunt	2	12.5
corpus alienum	1	6.3
TOFTotal Correction	3	18.8
VSD Closure	4	25.0
Total	16	100.0

Table 3: Stability check results

Variables		Week-6		Week-9		Week-12	
(sternal wire vs PDS)		Sternal wire	PDS	Sternal wire	PDS	Sternal wire	PDS
Pain	No				4	8	8
	Mild	2	8	5	4		

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	Mod	5		3			
	Sev	1					
	p-price	0.03		0.01		1.00	
Stability	Stable	8	6	7	5	8	5
	Minimal		2	1	3		3
	Partial						
	Complete						
	Harga p	0.143		0.264		0.063	
Displacement	Symmetrical	7	4	7	3	7	3
	Displace	1	4	1	5		5
	p-price	0.025		0.009		0.009	

Tabel 4: Healing rate results

Variable (sternal wire vs PDS)		Week-6		Week-9		Week-12	
		Sternal wire	PDS	Sternal wire	PDS	Sternal wire	PDS
Callus	Yes			3	2	5	3
	No	8	8	5	6	3	5
	p-price	1.00		0.602		0.333	
Manubrium (mm)		1.31 ± 0.125	1.47 ± 0.12	1.35 ± 0.16	1.75 ± 0.25	1.38 ± 0.20	1.92 ± 0.18
P		0.021		0.005		0.001	
Corpus (mm)		1.13 ± 0.08	1.21 ± 0.09	1.14 ± 0.07	1.38 ± 0.13	1.18 ± 0.06	1.53 ±0.36
P		0.094		0.001		0.019	
Lower sternum (mm)		1.16 ± 0.05	1.16 ± 0.10	1.16 ± 0.05	1.22 ± 0.07	1.18 ± 0.06	1.32 ± 0.15
P		0.728		0.105		0.029	

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Table 5: Average of gap increase

Variable (sternal wire vs PDS)	Week 6 to 9			Week 9 to12		
	Sternal wire	PDS	p	Sternal wire	PDS	p
Manubrium (mm)	0.04 ± 0.05	0.275±0.183	.004	-0.125 ± 0.125	0.175 ± 0.205	.105
Corpus (mm)	0.00 ± 0.00	0.175 ± 0.167	.004	0.05 ± 0.075	0..150 ± 0.340	.862
Lower sternum (mm)	0.00 ± 0.00	0.062 ± 0.074	.027	0.025 ± 0.07	0.01 ± 0.015	.239

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