Sacrospinosus Fixation Efectivity in Pelvic Organ Prolapse Patient

Efektivitas Fiksasi Sakrospinosus pada Penderita Prolaps Organ Panggul

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Abstract

Objective : to determine the effectiveness of SSF in patients with POP at dr. Mohammad Hoesin hospital (RSMH) Palembang

Methods : Randomized clinical trial (RCT) was performed at RSMH Palembang from January to September 2017. There were 30 samples of pelvic organ prolapse who met the inclusion criteria. Data frequency and distribution were described in table form, and the effectiveness of SSF was analysed by Wilcoxon / paired t-test while the effectiveness ratio was analysed by Mann Whitney / independent t-test. Data were analysed using SPSS version 16.0.

Results : There were no differences in patient characteristics (age, parity, body weight, height, and occupation) between the two treatment groups (p < 0.05). There were differences of breech pain (proctalgia) before and after 1, 3, and 6 months post operation in SSF group (p < 0.05), in which proctalgia was more exquisite after than before surgery. The results showed that SSF was effective in reducing urinary disorders, defecation disorders, vaginal prolapse, cystocele and rectocele, and effectively improving the quality of life of POP patients. In addition, there was a difference of proctalgia and vaginal prolapse 1, 3, and 6 months after surgery between two groups where the adverse outcome of the proctalgia was more significant in SSF group but the vaginal prolapse was more significant in the non-SSF group. There were no differences in bleeding complications (p = 1,000) and infection (p = 1,000) between the two groups.

Conclusions : Sacrospinous fixation effectively reduced the vaginal prolapse of pelvic organ prolapse patients.

Keywords : cystocele, defecation, proclatgia, quality of life, rectocele, sacrospinous fixation, urinary

Abstrak

Tujuan : untuk mengetahui efektivitas SSF pada penderita prolaps organ panggul di rumah sakit dr. Mohammad Hoesin (RSMH) Palembang

Metode : Uji klinis acak berpembanding (RCT) dilakukan di RSMH Palembang sejak bulan Januari sampai September 2017. Didapatkan sampel sebanyak 30 penderita prolaps organ panggul yang memenuhi kriteria inklusi. Frekuensi dan distribusi data dijelaskan dalam bentuk tabel dan efektivitas SSF dianalisis dengan uji Wilcoxon/paired t-test dan perbandingan efektivitas dianalisa dengan uji Mann Whitney/independent t-Test menggunakan SPSS versi 16.0.

Hasil : Analisis statistik tidak terdapat perbedaan karakteristik pasien baik usia, paritas, berat badan, tinggi badan, dan pekerjaan antara kedua kelompok perlakuan (p< 0,05). Didapatkan bahwa SSF efektif mengurangi gangguan berkemih, gangguan defekasi, prolaps vagina, sistokel dan rektokel serta meningkatkan kualitas hidup pasien POP, namun terdapat perbedaan nyeri bokong (proktalgia) sebelum dan sesudah 1 bulan, 3 bulan dan 6 bulan operasi pada group SSF (p <0,05). dimana proktalgia lebih dirasakan setelah operasi dibandingkan sebelum operasi. Selain itu terdapat perbedaan proklatgia dan prolaps vagina 1,3 dan 6 bulan setelah operasi antar kedua group dimana proktalgia lebih dirasakan pada kelompok SSF namun prolaps vagina lebih banyak dialami oleh kelompok non SSF. Tidak terdapat perbedaan komplikasi perdarahan (p = 1,000) dan infeksi (p = 1,000) antara kedua kelompok.

Kesimpulan : Fiksasi sakrospinosus efektif mengurangi prolaps vagina pasien prolaps organ panggul.

Kata kunci : berkemih, defekasi, fiksasi sacrospinosus, kualitas hidup, nyeri bokong, rektokel, sistoke

INTRODUCTION

Pelvic organ prolapse (POP) is one of common gynecology disorder which the incidence is increasing with the increasing life expectancy. POP does not cause death but can worsen patient's quality of life (QoL) by causing abnormalities of the bladder, gastrointestinal system as well as sexual dysfunction.¹

POP prevalence increased by 40% each additional decade of a woman's age. The prevalence of POP was differed by degrees, i.e., 28%-32.3% of grade I, 35% -65.5% of grade II and 2-6% grade III.² Currently, as many as 11-19% of women in developed countries undergo POP surgery, and the average age of women undergoing POP surgery is 60 years.³ In Dr. Cipto Mangunkusumo hospital, Junizaf et al reported 50% of parturient women would suffer from POP and almost 20% of gynaecological surgery is handling POP case.⁴ While Kemas A and Fauzi A report 43 cases of uterine prolapse in RSMH Palembang from 1999-2003.⁵

Sacrospinous ligament fixation (SSF) is an ideal vaginal procedure for repairing POP. Gayatri KB et al reported that SSF is a procedure which indicates for prolapse repair with success rate of 91%.⁶ There were significant differences in the severity of prolapse, cystocele, rectocele and QoL before and after surgery. SSF most specific complication is breech pain, which was found in 6/15 cases.⁶⁷

There is no data regarding SSF effectiveness, and adverse outcomes in POP patients POP at Palembang, especially in Dr. Moh. Hoesin hospital (RSMH) Palembang. Therefore, this study is expected to be used as initial information to improve the QoL of pelvic organ prolapse patients.

METHOD

Randomised clinical trials (RCT) study without comparison was done to assess the effectiveness of SSF in POP patients which performed at RSH inpatient Obstetrics and Gynecology care from October 2015 – September 2016. Study population was all POP patients who planned for operations at RSMH. The inclusion criteria include patients diagnosed with POP at any degrees (1, 2, 3 or 4), patients who will undergo POP operation (with or without SSF), willing to participate in the study by signing the informed consent. Exclusion criteria include patients with a history of micturition/ defecation problem preceding POP, suspected with malignancy, suffering diabetes mellitus, and not routinely control postoperative as scheduled.

Samples are patients who met the study criteria and selected by purposive sampling. Patient's history, physical examination, gynecologic examination, routine laboratory tests are all recorded on research sheet and empirically given a code number. The samples then underwent POP surgical correction with or without SSF. Patients were then followed up postoperatively at the 1st, 3rd, and 6th months with POP-Q assessment, defecation and micturition outcomes, breech pain, sexual function, and QoL. The obtained data were then recorded in the research sheet to be reported.

The dependent variable of the study is SSF, while independent variables comprise of POP-Q, breech pain, postoperative bleeding and infection, bladder disorders, bowel disorders, sexual function, and QoL. Shapiro-Wilk normality test was done to determine the data distribution, Chi-Square / Fisher's test was done for categorical data. SSF effectiveness analysed by Wilcoxon / paired t-test and comparison of its effectiveness was analysed by Mann Whitney test / independent t-test using SPSS version 16.0

RESULT

Sample's General Characteristics

Thirty selected sample were then divided into SSF group (n = 23) and Non SSF group (n = 7), and no drop out cases encountered. Matching were done on both group general characteristic variable (Table 6), where there were no differences in age (p = 0.309), parity (0.106), weight (p = 0.465), height (p = 0.90), address (p = 0.215) and occupation (p = 0.105) between both groups, means that analysis can be continued.

 Table 1.
 Sample's General Characteristic

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	Total	Gr	roup	P-value
Characteristic		SSF	Non-SSF	
Age (year), mean ± SD	61.53 ± 8.029	60.69 ± 8.177	64.29 ± 7.409	0.309*
Parity, mean ± SD	5.167 ± 2.35	4.783 ± 2.066	6.429 ± 2.936)	0.106*
Weight (kg), mean \pm SD	55.167 ± 8.575	54.522 ± 8.754	57.286 ± 8.220	0.465*
Height (cm), mean \pm SD	153.47 ± 4.769	152.65 ± 4.478	156.14 ± 5.047	0.090*
Address, n (%)				
- Palembang	11 (36.7)	10 (43.5)	1 (14.3)	0.215**
- Outside Palembang	19 (63.3)	13 (56.5)	6 (85.7)	
Occupation, n (%)				
- House wife	25 (83.3)	19 (82.6)	6 (85.7)	
- Entreprenuer	4 (13.3)	4(17.4))	0 (0)	0.105**
- Farmer	1 (3.3)	0(0)	1(14.3)	
Operation, n (%)				
- Kolp Anterior	25 (83.3)	23 (92.0)	2(28.6)	
- Kolp Posterior	1 (3.3)	0(0)	1(14.3)	0.000**
- Kolpokleisis	2 (6.7)	0(0)	2(28.6)	
- Kolp Anterior+ Kolp Posterior	2 (6.7)	0(0)	2(28.6)	

*Independent T Test,p = 0.05, ** Chi Square Test, p = 0.05

Preoperative Outcome Characteristic

Table 2 shows no significant differences in

The effectiveness of SSF in POP Patients

There were significant differences (p < 0.05) in

 Table 2. Preoperative Ouctome Characteristic

Characteristic		Group		
	SSF	Non-SSF		
Urinary Symptoms				
Mean ± SD	11.35±2.690	14.43±4.315	0.079*	
Median (Min-Max)	11 (8-16)	14 (9-22)		
Bowel Symptoms				
Mean ± SD	14.30±2.476	16.71±3.904	0.060**	
Median (Min-Max)	14 (10-19)	16 (11-22)		
Breech Pain				
Mean ± SD	1.522±0.79	2.286±1.976	0.590*	
Median (Min-Max)	1 (0-3)	1 (1-6)		
QoL				
Mean ± SD	29.57±7.391	35.71±9.032	0.077**	
Median (Min-Max)	30 (15-42)	37 (22-45)		
Vaginal Prolapse				
Mean ± SD	3.087±0.733	2.429±0.976	0.090*	
Median (Min-Max)	3 (2-4)	2 (1-4)		
Cystocele				
Mean ± SD	2.869±0.626	2.286±1.254	0.138*	
Median (Min-Max)	3 (1-4)	2 (0-4)		
Rectocele				
Mean ± SD	2.391±0.988	2.00±1.155	0.231*	
Median (Min-Max)	2 (0-4)	2 (0-4)		

*Independent T Test, p =0.05, Mean ± SD

**Mann-Whitney, p =0.05 , Median (Min-Max)

all preoperative outcome such as urinary and defecation symptoms, breech pain, QoL, vaginal prolapse, cystocele, and rectocele between the two groups.

urinary symptoms between preoperative and 1st, 3rd, and 6th month postoperative in both SSF and non-SSF groups in which urinary symptoms were significantly reduced after 1st, 3rd and 6th month

Table 2. Preoperative C	Ductome Characteristic
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Symptom	Month	SSF	Non-SSF	P-value
Urinary	1st	8.217±3.357	10.14±2.268	0.095*
	3rd	7.391±3.187	8.714±2.360	0.320*
	6th	7.435±3.615	8.000±2.236	0.700*
Bowel	1st	10.783±4.338	12.571±2.760	0.100**
	3rd	9.522± 4.347	11.286±3.039	0.109**
	6th	9.044± 3.548	9.714 ± 1.889	0.638*
Breech Pain	1st	8.478 ±3.073	1.286 ±0.488	0.000*
	3rd	5.826 ±2.657	1.143 ±0.690	0.000*
	6th	3,087 ±2,151	1.143± 0.069	0.020**
QoL	1st	24.304±11.121	20.286±6.969	0.122**
	3rd	19.261±11.343	18.429±8.142	0.825**
	6th	15.130±10.636	18.286±8.036	0.248**
Vagianal Prolapse	1st	0.000 ± 0.000	0.000 ± 0.000	1.000**
	3rd	0.000 ± 0.000	0.286±0.488	0.009**
	6th	0.130±0.344	0.571±0.535	0.018**
Cystocele	1st	0.000 ± 0.000	0.000 ± 0.000	1.000**
	3rd	0.000 ± 0.000	0.000 ± 0.000	1.000**
	6th	0.130±0.344	0.143±0.378	0.962**
Rectocele	1st	0.000 ± 0.000	0.000 ± 0.000	1.000**
	3rd	0.000 ± 0.000	0.000 ± 0.000	1.000**
	6th	0.348±0.487	0.000 ± 0.000	0.174**

*Independent T Test, p =0,05, Mean ± SD

**Mann-Whitney, p =0,05 , Median (Min-Max)

postoperation compared before operation in both groups. There were significant differences in bowel symptom before and after the 1st, 3rd, and 6th months of operation in both groups in which the symptom was felt to be reduced by both groups after 1st, 3^{rd,} and 6th months postoperation.

There were differences in breech pain before and after the 1st, 3rd, and 6th months of operation in the SSF group in which the breech pain, after 1 month postoperation, was felt significantly increase compared preoperation, but then decrease after 3 and 6 months postoperation. While in the non-SSF group, there were no significant differences in breech pain before and after surgery.

There were differences in QoL before and after 1st, 3rd, and 6th months of operation in both groups, where QoL improvement was perceived by both compared before the operation.

There were differences of vaginal prolapse before and after 1st, 3rd, and 6th months of surgery in both groups, whereas the vaginal prolapse

in SSF group was treated after 1 and 3 months postoperation, but relapse after 6 months postoperation. While in the non-SSF group, vaginal prolapse after 1 month of surgery was treated but relapse after 3 months of surgery.

There were differences of cystocele before and after 1st, 3rd, and 6th months after surgery in both groups, where the cystocele in both groups was treated after 1 and 3 months of surgery but relapse after 6 months of operation.

There were rectocele differences before and after 1st, 3rd, and 6th months after surgery in both groups, where rectocele in SSF group after 3 months of surgery is reduced compared before surgery, but relapse after 6 months of surgery. While in non-SSF group rectocele after 1 month of operation was decreased compared before surgery and stay until 6 months after surgery.

There were significant differences in urinary symptoms, defecation symptoms, QoL, cystocele and rectocele 3 months after surgery between the two groups. However, there was a significant difference of breech 3 months after surgery between the two groups, where SSF group complained of more severe breech pain compared with non-SSF, and there were significant differences in vaginal prolapse between the two groups 3 months after surgery where vaginal proplase in non-SSF were more severe than SSF group.

There were no significant differences in urinary symptoms, defecation symptoms, QoL, cystocele and rectocele 6 months after surgery between the two groups. However, there were significant differences in breech pain 6 months after surgery between the two groups in which the SSF group experienced more severe breech pain compared than non-SSF group, and there were significant differences in vaginal prolapse 6 months after surgery between the two groups in which the non-SSF group experienced more severe vaginal prolapse compared than the SSF group.

DISCUSSION

In this study, the mean age of POP patients is +61,5 years old with range 40-78 years. The results of this study are similar to Slieker et al which stated that the average age of POP patients is 58 years with range 45-85 years.⁸ Decreased estrogen levels in postmenopausal period, as well as the physiological aging process in various anatomical structures of the pelvic floor related to pelvic floor dysfunction. Swift et al showed increasing of POP odds ratio from 1.04 to 1.46 in the period of 10 years.⁹

Based on parity POP patients had ± 5 with range of 1-11. In an epidemiological study conducted by the Oxford Family Planning Association, shows that parity is the strongest risk factors that affect POP occurrence with adjusted relative *risk* of 10,9. Samuelsson et al. also found a significant association between high parity and POP. Damage to the pelvic floor muscles and fascia as a result of pregnancy and childbirth contribute to the occurrence of POP.¹⁰

Most POP patients in this study were housewive. Chiaffarino et al. showed that housewives had significantly higher risk of prolapse compared to career women due to more physical work (n = 208; OR: 3.1, 95% CI: 1.6 to 8.8).¹¹

After surgery, we found significant differences in urinary symptoms before and after surgery,

where the urinary problems that which felt by both groups after 1st, 3rd, and 6th months of surgery is reduced compared before surgery. These results are consistent with research conducted by Dietz in 2010 which showed a significant decrease of urinary symptoms before and after surgery (p <0.05).¹²

In addition, there were no differences of urinary symptoms 1^{st} , 3^{rd} and 6^{th} months after surgery (p> 0.05) between the two groups. This result is similar with HJ Van Brummnen et al who compared the effects of urinary symptoms among respondents with SSF and non SSF, where no differences in urinary symptoms such as overactive bladder (p = 1.000), stress incontinence (p = 1.000) as well as urge incontinence (p = 0.250).¹³ This results also supported by Dietz et al (2010) where there were no differences between in urinary symptom such as overactive bladder symptoms (p = 0.9) and urinary incontinence (p = 1.000) among SSF and non-SSF group.¹² The mechanism of urinary symptom that occurs in patients with POP is unclear, but there is probability that blunt dissection of the bladder from uterus and cardinal ligaments may damage the main branches of the pelvic plexus and affect the detrusor inervation.¹⁴⁻

There are significant differences in bowel disorder before and after surgery in both groups (p < 0.05), in which the bowel disorder is perceived lower after 1st, ^{3rd}, and 6th months post operation compared before operation by both groups. In addition, there is no significant differences in bowel symptoms 1st, 3rd, and 6th months after surgery (p > 0.05) between the two groups. This result is in line with Dietz's research in 2010 showing a significant decrease in symptoms of defecation before and after surgery (p < 0.05).¹²

There were differences in breech pain before and after operation in SSF group. While no differences were found in non-SSF group (p> 0.05). Breech pain which felt post operation was gradually diminished at 3rd and 6th months postoperatively. In addition, there were significant difference in breech pain between the two groups, in which breech pain in the SSF group was felt more severe than the non-SSF. These results are similar to studies by Karam and Walters which suggest that breech pain is a common complication after SSF surgery with a

prevalence of 10-15%.17.18

Postoperative complications can be reduced by understanding the risk of surgical procedures, including the risks of anesthesia, position, surgical techniques, implants, and infection. Neurapraxia can be avoided by correct position and giving a pedestal at the pressure points. In the modified lithotomy position for sacral colpopexy, femoral nerve injury may occur due to hyperextension of the hip and should be avoided. Placement of retractors for surgical field exposure can cause nerve injury, commonly the femoral nerve because the nerve passes through the psoas muscle. Nerve injury is commonly found as a postoperative complication, in addition, may cause motor and sensory impairment. Postoperative pain may be caused by nerve injury due to improper patient positioning during surgery. Perineal nerve injury can result from pressure if the patient is not positioned correctly and given a pad.^{14,15}

Dietz study (2010) showed a significant decrease in impaired QoL before and after surgery (p < 0.05). Aigmuller et al in 2007 also shows a good quality of life outcomes in which the rate of satisfaction after surgery is quite high. ^{12,16}

Furthermore, it was found that vaginal prolapse in SSF group after 1 and 3 months postoperation is reduced but relapse after six months of surgery. While vaginal prolapse in the non-SSF group was also reduced after one month of surgery, but relapse after three months of operation. Additionally, there were differences in vaginal prolapse in 3 and 6 months after surgery between the two groups. These results are consistent with Dietz et al (2010) where there was a significant difference in the incidence of vaginal prolapse between the two groups (p = 0.031). The results also supported by TVL difference between the two groups with a p-value <0.01 (8.8 \pm 1.3 vs 7.3 \pm 1.5).¹²

For cystocele and rectocele outcome we found that cystocele in SSF and non-SSF group were treated after surgery, but relapse after six months of surgery. In addition, there were no differences in the incidence of cystocele and rectocele after surgery between the two groups (p > 0.05). The results are in line with Van Brummnen HJ et al where there are no differences in the anatomy outcome (cystocele, rectocele, enterocele & uterine prolapse) between SSF and non SSF group.¹³ Furthermore, Dietz et al (2010) also support this research results which no differences were found in cystocele (p = 0.099) and rectocele (p = 0.255) between SSF and non SSF group.¹²

A retrospective cohort study by Smilen et al in 1998 concluded that there was an increase in the incidence of cystocele after SSF surgery.¹⁹ Aigmuller et al (2007) found a 29% incidence of cystocele, 5% rectocele, and 7% vaginal prolapse after SSF surgery. Likewise, Dietz (2008) who found 13.9% of cystocele incidence and 2.8% of rectocele incidence.^{14.16}

There were no differences in postoperative bleeding and infection between two groups. The results of this study were differed from Dietz's study in which no complications were found during vaginal hysterectomy with SSF.¹² Procedure of SSF may have some complications, bleeding occurs in 1 in 100 patients.²⁰ The difference in bleeding complications with some studies may be caused by the resident role as the operator, while postoperative infection in some samples may not solely be caused by the surgery.

CONCLUSIONS

Sacrospinous fixation is effective in reducing vaginal prolapsed in POP patients.

SUGGESTION

Further studies are needed to see how much SSF, as a risk factor, affect postoperative breech pain in patients with pelvic organ prolapse.

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