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COMPARISON OF OUTCOME OF ASARP VS PSARP IN REPAIR OF RECTOVESTIBULAR FISTULA; A RANDOMIZED TRIAL

Ammar Waqas[1], Muhammad Bilal Mirza[2], Hassan Mahmood[3], Muhammad Faisal[*4], Muhammad Umair Arshad[5], Soban Hameed[6]

[*4]faisalqaisrani123@gmail.com

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Corresponding Author: *
Muhammad Faisal

Abstract

Background: *Anorectal malformations are birth deformities in which the anus is absent or deformed. It affects both males and females and has a prevalence of one in 5000 live births. Recto vestibular fistula is the most common type of female congenital anorectal abnormality that presents to the pediatric surgeon in early life for surgical repair. In this case, the rectum terminates with a fistula to the vestibule. Anatomically, the main character of this deformity is common wall between rectum and vagina. On correct management of rectovestibular fistula, it shows excellent prognosis with respect to function. From ancient times, there are multiple operative techniques described in literature for the management and treatment of vestibular fistula which including posterior sphincter called posterior sagittal anorectoplasty (PSARP), and anterior to sphincter called anterior sagittal anorectoplasty (ASARP). The Posterior Sagittal (PSARP) or Anterior Sagittal (ASARP) ano-recto plasty are the most commonly performed procedures in the treatment of vestibular fistulas. This study aimed to compare the results of this alternative approach of ASARP to a well-established procedure of PSARP in the therapy of vestibular fistula.*

Methods & Materials: *A Randomized controlled trial registered with TCTR with trial number (TCTR20250313005) is conducted at Department of Paediatric Surgery, The Children's Hospital and The University of Child Health, Ferozpur Road, Lahore from January 2023 to January 2024. Non-Probability purposive sampling was taken. Allocation of treatment was ensured using balloting method.*

Results: *Group A and group B are comparable with respect to age, weight, duration of surgery and hospital stay. Group A has 56.7% complication rate while Group B has 50% complications. Group A has 6.7% procedural injuries, 33.3% anal stenosis and mucosal prolapse in 10% while group B has 10%, 30% and 6.7% respectively. On TENS application, ASARP group has good contractions all around in 80% of patients and weak on one side in 20% while PSARP group has good contractions all around in 80% of patients, weak on one side in 16.7% of patients while weak all around in 3.3% patients. With respect to wound infection, disruption and retraction, group A has 6.7%, 10% and 6.7%, respectively while group B has 10%, 13.3% and 0% respectively.*

Conclusion: *ASARP and PSARP are two well established techniques in the management of vestibular fistula. Many studies determine ASARP as less time consuming and with less complications, but it is not proven statistically. In this study, we found both the techniques comparable with respect to early and late*

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complications and functional ability of the patients. Further study with large sample size is required to establish a significant difference between the two techniques.

INTRODUCTION:

Anorectal malformations are birth deformities in which the anus is absent or deformed. It affects both males and females and has a prevalence of one in 5000 live births. ARM is a combination of disorders including simple issues like anal stenosis and fistula in perineum which are grouped as low variety malformation to very complex anomalies which include persistent cloaca and recto-vesical fistulas which require multistage procedures for correction. Recto vestibular fistula is the most common type of female congenital anorectal abnormality that presents to the pediatric surgeon in early life for surgical repair. (Sloan and Wagener,2016). On examination of perineum, a normal urethra along with a normal vagina is found and another opening in the vestibule is found behind the vaginal opening. In this case, the rectum terminates with a fistula to the vestibule. Anatomically, the main character of this deformity is common wall between rectum and vagina. (Hasina et al., 2014, Levitt et al., 2009) This diagnosis is made clinically with careful and detailed examination of the baby's perineum. On examination, there is flat buttocks with no anal opening and another hole in the introitus at the level of posterior fourchette via which stool pass (the other two being the urethra and the vagina) (Hasina et al., 2014).

On correct management of rectovestibular fistula, it shows excellent prognosis with respect to function. Ironically, girls who have these abnormalities experience further problems following an unsuccessful effort at correction. From ancient times, there are multiple operative techniques described in literature for the management and treatment of vestibular fistula which include anal transposition, cutback anoplasty, X-Z and Y-V plasty, repair through perineum including region posterior sphincter called posterior sagittal anorectoplasty (PSARP), and anterior to sphincter called anterior sagittal anorectoplasty (ASARP). The Posterior Sagittal (PSARP) or Anterior Sagittal (ASARP) ano-recto plasty are the most commonly performed procedures in the treatment of vestibular fistulas and consist of series of steps for replacement of anus and reconstruction of the recto-perineal complex. We decided to compare the results of this alternative approach of ASARP to a well-established procedure of PSARP in the therapy of vestibular fistula.

METHODS AND MATERIALS:

This Randomized controlled trial, is registered with TCTR with trial number (TCTR20250313005) ,was conducted in the Department of Paediatric Surgery, The Children's Hospital and The University of Child Health, Ferozpur Road, Lahore. This study continued for 12 months after the approval from IRB. A total of 60 patients were included in the study, 30 in each group. Non-Probability purposive sampling was used for enrollment of patients and treatment was allocated using balloting method. All-female patients with rectovestibular fistula with sigmoid colostomy, aged between 6 months to 14 years having weight 5 kg and above were included in this study. All the patients were regularly followed for evaluation and comparison of outcomes and complications.

RESULTS:

A total of 60 patients were included in this study (30 in each group). In ASARP group, the mean age of patients was 40.57 months while in PSARP, mean age was 47.93 months. The mean weight of the patients in ASARP group was 12.80 kg while in PSARP group was 14.93 kg.

The mean duration of surgery was 120.60 min in ASARP as compared to 116.47 min in PSARP. In ASARP group, 53.5% patients were discharged on 3rd day as compared to 73.3% patients in PSARP group and only 3.3% patients were discharged on 6th day in both groups. 56.7% patients in ASARP group developed intra or post operative complications whereas only 50% patients in PSARP patients developed complications. With

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respect to procedural injury, ASARP group has 6.7% injuries while PSARP group has 10% injuries.

In ASARP group, 80 % patients had contractions equal and strong all around, 20% patients had contractions weak on one side while strong contractions on other side whereas no patient had contractions weak all around. Whereas in PSARP group, 80% patients had contractions equal and strong all around, 16.7% patients had weak contractions on one side and strong contractions on other side while 3.35 patients had contractions weak all around.

In ASARP group, 33.3% patients had anal stenosis, 10% had mucosal prolapse and 6.7% had retraction as compared to 30%, 6.7% and no retraction in PSARP respectively.

In ASARP group, 6.7% patients had superficial SSI, 16.7% patients had deep SSI and10% had wound disruption whereas in PSARP group, 10% patients had superficial SSI, 13% patients had deep SSI and 13.3% had disruption.

Table 1: Demographic Data

Sr. No.	Variable	ASARP	PSARP
1.	Mean Age	40.57 months	47.93 months
2.	Weight	12.80 kg	14.93 kg
3	Duration of surgery	120.60 min	116.47 min

Table 2: Hospital Stay (days)

Sr. No.	Technique	Days					Total	P-value
		2	3	4	5	6		
1	ASARP	2(6.7%)	16(53.3%)	8(26.7%)	3(10%)	1(3.3%)	30	3.840
2	PSARP	0	22(73.3%)	5(16.7%)	2(6.7%)	1(3.3%)	30	
Total		2	38	13	5	2	60	

Table 3: Complications

Sr. No.	Variable	ASARP		PSARP		P-value	TOTAL
		Yes	No	Yes	No		
1.	Complications	17 (56.7%)	13 (43.3%)	15 (50%)	15 (50%)	0.077	60
2.	Procedural Injury	2 (6.7%)	28 (93.3%)	3 (10%)	27 (90%)	0.218	60
3	Anal Stenosis	10 (33.3%)	20 (66.7%)	09 (30%)	21 (70%)	1.020	60
4	Mucosal Prolapse	3 (10%)	27 (90%)	2 (6.7%)	28 (93.3%)	0.311	60
5	Repair Disruption	3 (10%)	27 (90%)	4 (13.3%)	26 (86.7%)	0.162	60
6	Retraction	2 (6.7%)	28 (93.3%)	0	30 (100%)	2.069	60

Table 4: Nerve conduction Study

Sr. No.	N	Technique	Contractions Equal & Strong all around	Weak on one side while Strong on other side	Contractions Weak all around	P-value
1	30	ASARP	24 (80%)	6 (20%)	0	1.020
2	30	PSARP	24 (80%)	5 (16.7%)	1 (3.3%)	
Total	60		48 (80%)	11 (18.3%)	1 (3.3%)	

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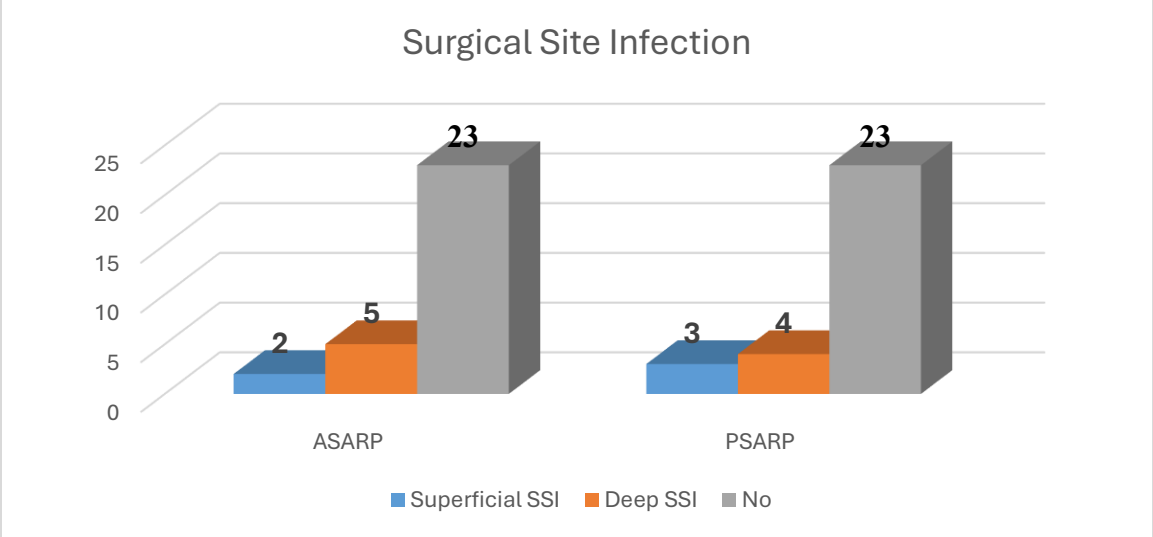


Chart No. 1: SSI

DISCUSSION:

This randomized controlled trial evaluated and compared the outcomes of anterior sagittal (ASARP) and posterior sagittal (PSARP) anorectoplasty in vestibular fistula patients. Techniques were compared with respect to procedure duration, hospital stay, intra operative complications and post operative complications.

The results in the current study showed that both the techniques were comparable with respect to age and weight of the patients. With respect to duration of surgery, a few patients with ASARP took more time than PSARP. Mean time of surgery in ASARP is 120 ±20 mins and in PSARP 116 ± 21 min. This finding contradicts with **Negm MA et al.** study and **Aziz Md et al.** study which showed mean time in ASARP is 87.38±5.62 mins and 90 mins respectively. **Kursunge et al.** showed that mean time of surgery in PSARP is 94.89 ± 10 mins which is near to our findings. **Shehata** described that there is no difference in operating time in ASARP and PSARP (i.e 80 mins). Duration of surgery is surgeon dependent and can vary in different studies. Different surgeons performed operations in our study. Minimum time is 70 min in our study.

According to **Negm et al.,** the hospital stay in ASARP patients is 5.48±1.44 days. **Aziz Md et al.** also described mean hospital stay 6 days in ASARP patients. In PSARP **Kursunge et al.** mentioned hospital stay in his study was 8.36 ± 3.96 days while **Laddha et al.** found it 7.52 ± 1.91 days. Our finding differs from all these studies showing that mean hospital stay in both ASARP and PSARP group was 3.50±0.9 days and 3.40±0.77 days respectively. (25) This difference is probably due to our ward policy. We believe in early discharge if no issue is identified hence short hospital stay in our study.

ASARP group has more over all complication rate (56.7%) as compared to PSARP group (50%) but this finding could not reach to the level of statistical significance. In the current study, procedural injuries were included vaginal and rectal injuries. Fortunately, we did not find any rectal injury but vaginal injury in 2(6.7%) patients in ASARP and 3 (10%) patients in PSARP. Similar findings were described by **Negm et al.** showing vaginal injury in 2(5.26%) ASARP patients. **Harjai MM et al.** found 3(20%) patients with vaginal injury and no rectal injury in ASARP just like us but 2(16%) patients with rectal and vaginal injury in PSARP contrary to us. **Abdelmohsen et al.** mentioned 1(7.7%) patient having vaginal wall injury in ASARP and no vaginal injury in PSARP patients and no rectal injury in either ASARP or PSARP group.

Mucosal prolapse found by **Negm et al.** in his study was 5(13.15%) patients undergone ASARP. **Elrouby et al.** also mentioned mucosal rectal prolapse in 20 (3.4%) patients having ASARP. In our study, we found prolapse in 3(10%) patients

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having ASARP which is near to Negm's finding and 2(6.7%) patients having PSARP. Whereas **Harjai et al.** described 1(6%) prolapse in ASARP patients and 1(8%) prolapse in PSARP patients. **Abdelmohsen's** findings contradicts with all these. He showed 4(20%) prolapse in PSARP patients whereas only 1(7.7%) in ASARP patients.

In the current study, wound infection was found to be 23.4% (superficial and deep) in ASARP group and 23% in PSARP group. **Shehata** and **Saoji R et al.** described infection rate of 26% and 18% in PSARP group but only 11%and 9% in ASARP group respectively. Similarly, **Harjai et al.** mentioned infection rate in ASARP group was 20% and 25% in PSARP group which in close to our findings. **Abdelmohsen et al.** found highest infection rate in ASARP group (30.8%) contrary to rest of studies but similar rate in PSARP group (26.3%).

With respect to wound disruption or dehiscence and retraction, we found 10% and 6.7% in ASARP group and 13.3% and 0% in PSARP group respectively. **Wakhlu et al.** found only 0.3% wound dehiscence and 0.4% retraction in ASARP group. **Elrouby et al.** observed only 1% patients with retraction after ASARP. **Kursunge et al.** described only 5.5% patients having dehiscence and no patient with retraction after PSARP. **Harjai et al.** mentioned 6% patients had dehiscence after ASARP and 8% patients had dehiscence after PSARP. **Saoji R et al.** said that only 4.5% patients had wound dehiscence and rectal retraction after PSARP and no dehiscence after ASARP. Follow up surgeries were included in our study but all patients having disruption were reoperated and recovered after second surgery.

In this study, we observed anal stenosis in 33% patients after ASARP and 30% patients after PSARP. Stenosis in our study is very high with respect to other studies. **Wakhlu et al.** found only 0.16% anal stenosis in patients after ASARP. **Elrouby et al.** described only 5% patients had anal stenosis after ASARP. **Abdelmohsen et al.** mentioned anal stenosis in 15.8% patients after PSARP and 15.4% patients after ASARP. **Laddha et al.** found 6.5% patients had anal stenosis after PSARP. This high incidence of anal stenosis in our study is most likely due to including all patients having dilatable stenosis. All these patients were managed with dilatation program and no surgery was required for any of these patients.

On application **of TENS**, both the groups had comparable sphincter muscle contractions. In our study, 3.3% patients had poor contractions all around in PSARP group while no patient had poor contraction all around in ASARP group. This is likely due to extensive dissection in PSARP as compared to ASARP.

CONCLUSION: ASARP and PSARP are two well established techniques in the management of vestibular fistula. Many studies determine ASARP as less time consuming and with less complications, but it is not proven statistically. In this study, we found both the techniques comparable with respect to early and late complications and functional ability of the patients. Further study with large sample size is required to establish a significant difference between the two techniques.

Conflict of interest: There was no conflict of interest in this study

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