



OUTCOME OF POSTERIOR SAGITTAL ANORECTOPLASTY IN ANORECTAL MALFORMATIONS WITH AND WITHOUT FISTULA IN TERTIARY CARE CENTRES OF NORTH INDIA

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ABSTRACT

Introduction: Anorectal malformations (ARM) have been a source of concern for centuries. The reported incidence of ARM is 1 in every 2500 to 5000 live births^{1,2} but maybe even more frequent in certain developing countries^{3,4,6-24}. Although ARM comprise approximately 0.2-0.3% births. They have been reported to comprise up to 1.2% of reported birth defects. Approximately 36.4% are isolated lesions and 63.6% are associated with other anomalies⁵. Studies demonstrated several mutations of HLXB9 associated with ARM²⁵. **Method and Material:** 33 patients with intermediate ARM were included. A thorough perineal examination, complete haemogram, urine analysis, colposcopy and radiological studies were conducted. Patients underwent PSARP, the comparison of late complications and functional outcome at the end of 1 year follow-up in ARM patients with and without fistula was done. Fischer Exact Test was done for getting Two tailed P-value. **Observation and Results:** Out of 33 patients 16 males were without fistula and 17 males were with rectourethral fistula. 33 patients underwent PSARP, 8 cases (24.24%) had early complications. Late complications in 12 cases (36.36%). No post-operative complications were recorded in 13 (39.39%) children. At end of follow-up, 31 remaining patients (including patients with superficial wound infection) had normal looking perineal body and anus with good contraction. No recurrence of fistula, stenosis of anus or anterior displacement of rectum. **Conclusion:** PSARP is a useful procedure for the correction of ARM in children in developing countries and quality of life depends on clinical status of patient and age at the time of presentation. No significant statistical differences in quality of life was seen in patients with fistula vs patients without fistula post PSARP.

KEYWORDS : Anorectal malformation (ARM), Complications of ARM, Intermediate ARM.

Introduction:

Anorectal malformations (ARM) have been a source of concern for centuries. The reported incidence of ARM is 1 in every 2500 to 5000 live births^{1,2} but maybe even more frequent in certain developing countries^{3,4,6-24}. Although ARM comprise approximately 0.2-0.3% births. They have been reported to comprise up to 1.2% of reported birth defects. Approximately 36.4% are isolated lesions and 63.6% are associated with other anomalies⁵. Studies demonstrated several mutations of HLXB9 associated with ARM²⁵. In 1984, Prof. D. Stephens and Prof. D. Smith proposed Wingspred classification^{26,27}. This classification also included the special groups in cloacal and rare malformations. In 1995 Pena introduced a disparate classification system. May 2005, 21 years after the Wingspread classification The Pena's classification was modified at Krickenbeck meeting²⁸

Material and Method

This one year prospective study "Outcome of posterior sagittal anorectoplasty in anorectal malformations with and without fistula in tertiary care centres of North India" was undertaken between September 2018 to August 2019 at the Post graduate Department of Surgery, S. R. N Hospital and Sarojini Naidu Children's hospital associated with M.L.N Medical College, Allahabad and other hospitals across North India after approval from the ethical committee and with written and informed consent of legal guardians of patients.

33 patients who underwent PSARP for Intermediate Anorectal Malformation, with and without fistula were included in the study.

A thorough perineal examination, complete hemogram, urine

analysis, fistulogram, colposcopy, radiological and ultrasonographic studies were conducted. Using clinical evaluations, cross table lateral decubitus X-rays (with pubococcygeal line or PC line as a guide), lower vertebral X-ray, pelvic ultrasound scan, echocardiography and CT scan.

Method

PSARP described by Pena was carried out while the babies were secured in a jack-knife position (prone and knell-elbow position with buttocks elevated). Antibiotics and analgesics comprising of ceftriaxone (75 mg/kg/24 h), metronidazole (7.5 mg/kg/dose), and tramadol (0.5 mg/kg/dose) were commenced at induction of anesthesia and continued for 72 h. Oral feeds and wound inspection/warm saline irrigation were commenced on the second post-operative day. Serial anal dilatation which was demonstrated to the parents who continued with it at home was started on the seventh post-operative day (Table 1). Anal dilatation was commenced earlier than standard protocol which should start at two weeks post-operative to reduce cost of hospitalization and risk of nosocomial infection in these neonates. The babies were thereafter discharged to follow-up at the surgical outpatient clinic. The follow-up protocol was a twice a week visit for one month, weekly visit for two months, bi-monthly visit for six months and monthly visit thereafter.

The duration of follow-up was 1 year. History of defecation and examination of anus, perianal region, perineum was included in routine follow-up. Every patient was advised regular anal dilatation with an appropriate size anal dilator after a period

of 2 months for the period of 4 to 6 months after PSARP

Table 1: Size of Hegar dilator according to age

| Age | Size | Tapering Frequency | Duration (months) |
|-------------|------|--------------------|-------------------|
| 1-4 months | #12 | Daily | 1 |
| 4-8 months | #13 | Every third day | 1 |
| 8-12 months | #14 | Twice per week | 1 |
| 1-3 years | #15 | Once per week | 1 |
| 3-12 years | #16 | Once per month | 3 |
| >12 years | #17 | | |



Hegar dilator

All 33 patients were neonates at the time of surgery. Functional outcome could not be determined according to one prescribed scoring system because of lack of capacity to verbalize during time period of study. Instead mothers were interviewed regarding number of bowel movements, loose stools and soiling complaints; anal inspection and digital rectal examination (DRE) were performed with the patient in the left lateral position with adequate illumination. Digital rectal examination was performed by inserting a lubricated, gloved index finger into the rectum to assess the presence or absence of an EAS defect and to determine resting and incremental squeeze pressure. Either resting pressure or incremental squeeze pressure was scored as "normal", "decreased" or "absent" at the discretion of the investigator. (Table 7)

PSARP was performed and patients were observed for postoperative complications, functional outcome and quality of life pertaining to normal bowel movement.

The comparison of late complications and functional outcome at the end of 1 year follow-up in anorectal malformation with fistula vs without fistula post PSARP using Fischer Exact Test for getting Two tailed P- value. The comparison will be considered significant if Two Tailed P-value will be < 0.05. We could not deduce p- value for comparison between PSARP in ARM with and without fistula having early complications as the value include "0" in the table.

PARTICIPANTS

All post-operative patients who underwent PSARP for intermediate type ARM patients and were attending surgery OPD of various tertiary care hospitals of north India from September 2018 to 2019.

Inclusion Criteria

- Must be ARM.
- Must be intermediate type ARM (Based on Wingspread classification)
- Weight more than 2.5 kg.
- Presentation during the first week of life in clinically stable condition.
- Absence of life threatening associated congenital anomaly (especially cardiac)
- Absence of gross abdominal distension, splinted diaphragm and/or evidence of aspiration before presentation.

- Hemogram and blood chemistry within normal ranges.
- Patient's guardian must be able to understand and follow study related advices.
- Patient's guardian must be able to understand and give consent for study.

Exclusion Criteria

- Serious life threatening illness.
- Associated with NEC and perforation.
- Conditions which might interfere with assessment, safety, results and outcomes of study.
- Inability to understand and give consent.

Target Conditions

- Continence
- Normal bowel movement
- Fistula repair and closure
- Anal opening at natural site of perineum



PSARP-Mobilization of rectum with Fistula

Observations and Results

In total, 52 children with anorectal malformations, 1 day to 2 months old (median age 2 days) were treated during the period of study. (Table 3). 12 females (23.07%), Male: female ratio 3.3:1. These comprised of 13 (25%) with low, 33 (63.46%) with intermediate and 6 (11.54%) with high anomalies.

36 (69.23%) patients out of 52 were diagnosed with fistula and 16 (30.77%) were without fistula. Table 2

Table 2

| Type of ARM | With fistula | Without fistula |
|--------------|--------------|-----------------|
| Low | 13 | 0 |
| Intermediate | 17 | 16 |
| High | 6 | 0 |
| Total | 36 | 16 |

Table 3: Distribution of patients according to time of presentation

| Time of Presentation | No of patients |
|----------------------|----------------|
| 1 day | 16 |
| 2 days | 8 |
| 3 days | 8 |
| 5 days | 7 |
| 1 week | 2 |
| 2 weeks | 3 |
| 10 days | 2 |
| 1 months | 5 |
| 2 months | 1 |
| Total | 52 |

Table 4: Demographic Data

| | |
|-----------------------|-------------------|
| Total no. Of patients | 52 |
| Males | 40 |
| Females | 12 |
| Age range | 1 day to 2 months |

| | |
|------------------------|--------|
| Median age | 2 days |
| Total High ARM | 6 |
| Total intermediate ARM | 33 |
| Total low ARM | 13 |

During first postoperative week, all 32 (one patient succumbed to fatal septicemia) patients were examined for early complications like wound infection, dehiscence, rectal retraction or perianal excoriation. Later, emphasis at follow-up was given on bowel habits, continence, need for laxatives, neo-anal stenosis, anterior anal displacement.

Thirty three patients on whom PSARP was performed, 8 cases (24.24%) had early complications. Late complications were found in 12 cases (36.36%). No post-operative complications were recorded in 13 (39.39%) children.

Early Complications

Table 5: Early Post operative Findings

| | With fistula (n=17) | Without fistula (n=16) |
|------------------------------|---------------------|------------------------|
| Surgical site infection | 3 | 0 |
| Septicemia | 0 | 1 |
| Urethral injury | 1 | 0 |
| Wound dehiscence | 0 | 1 |
| Wound abscess | 1 | 0 |
| Transient neurogenic bladder | 1 | 0 |

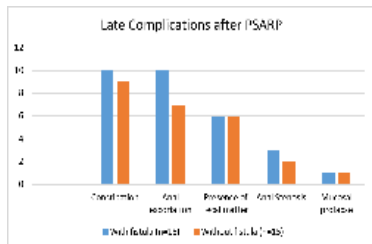
p- value is >0.05, thus showing that there is no significant difference in early post operative findings among patients with fistula and without fistula.

Late Complications

Table 6: Late Postoperative Complications

| | With fistula (n=16) | Without fistula (n=15) | P- value (Significant < 0.05) |
|--------------------------|---------------------|------------------------|-------------------------------|
| Constipation | 10 | 9 | 1.00 |
| Anal excoriation | 10 | 7 | 0.47 |
| Presence of fecal matter | 6 | 6 | 0.70 |
| Anal Stenosis | 3 | 2 | 1.00 |
| Mucosal prolapse | 1 | 1 | 1.00 |

p- value is > 0.05, showing that there is no significant difference in the rate of occurrence of constipation (p=1.0), incontinence (p=0.43), anal excoriation (p=0.47), mucosal prolapse (p=1.0), anal stenosis (p=1.0) and presence of faecal matter on anal inspection (p=0.70) in the patients of with and without fistula.

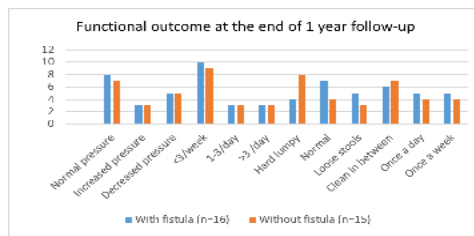


29% (9 out of 31) patients reported grade 2 incontinence which completely resolved with toilet training and dietary management over course of one year follow-up.

16% (5 out of 31) patients developed anal stenosis by third post-op week, they were more frequently followed up for anal dilatation under supervision in OPD by following protocol mentioned in Table 1.

Table 7- Outcome at end of 1 year follow-up in children less than 6 months at the time of PSARP

| | | With fistula (n=16) | Without fistula (n=15) | p- value (significant < 0.05) |
|----------------------------------|--------------------|---------------------|------------------------|-------------------------------|
| DRE (Digital rectal examination) | Normal pressure | 8 | 7 | 1.00 |
| | Increased pressure | 3 | 3 | 1.00 |
| | Decreased pressure | 5 | 5 | 1.00 |
| No of bowel movements | <3/week | 10 | 9 | 1.00 |
| | 1-3/day | 3 | 3 | 1.00 |
| | >3 /day | 3 | 3 | 1.00 |
| Type of stools | Hard lumpy | 4 | 8 | 0.28 |
| | Normal | 7 | 4 | 0.45 |
| | Loose stools | 5 | 3 | 0.69 |
| Soiling | Clean in between | 6 | 7 | 1.00 |
| | Once a day | 5 | 4 | 0.69 |
| | Once a week | 5 | 4 | 1.00 |



The p-value of >0.05 in DRE examination results, number of bowel movements, types of stool and frequency of soiling shows that there is no statistically significant correlation in outcome pertaining to absence or presence of fistula.

Other Findings

7 out of 8 patients with loose stools and 5 out of 6 patients with more than 3 bowel movements per day also complained of anal excoriation. Statistically significant relationships p=0.006 was seen in anal excoriation among patients with loose stools and anal excoriation among patients with more than 3 bowel movements per day.

Out of 9 patients with grade 1 incontinence (soiling once a day) 6 had excoriation and 3 did not have excoriation. P=0.059 proves no statistically significant correlation between anal excoriation and grade 2 incontinence.

Out of 10 patients with decreased pressure on DRE excoriation was present in 4 and absent in 6. No significant correlation between anal excoriation and decreased pressure on DRE proved by p=0.107

Out of 15 patients with normal DRE, 6 were completely clean in between bowel movements, 4 showed staining less than once a week and 5 soiled clothes in between bowel movements once a day. No statistically significant correlation between normal DRE and patient being clean in between bowel movements proved by p=1.0.

At end of follow-up, 31 remaining patients (including patients with superficial wound infection) had normal looking perineal body and neo-anus with good contraction. There was no recurrence of fistula in any patient. No patient had stenosis of neo-anus or anterior displacement of rectum. The neo-anus for all patients was calibrated to size of Hegar dilator as shown in Table 1.

Discussion

This study is consistent with the findings of other workers that low and intermediate ARMs are more common than high ARMs, and boys are affected more than girls^{29,30}. The study demonstrated low ARMs in 13 children, intermediate ARM in 33 while high variety in 6, with a male to female ratio of 3.3:1. This gender ratio is higher than the reported range of 1.2:1 to 1.8:1^{31,32}

In current prospective study 23 out of 36 (63.8%) fistulas were associated with high and intermediate ARM; a finding congruent with another study with fistulas being identified in 53% of isolated supralevator lesions and in only 37% of infralevator lesions.³³

We found 100% incidence of fistula in females and 61.90% incidence in males which is comparable to the results in The Surgical Section of the American Academy for Pediatrics,³⁴ study which reported a 90% incidence in girls and 72% incidence of fistula in boys.

As with other literature and studies done in the past this study reiterated the fact that the most frequent functional disorder encountered after treatment for imperforate anus in which the rectum has been preserved is constipation^{34,35}

Though fecal incontinence causes more physical and psychological discomfort to patients, constipation is the most common complication³⁶ and a complication that pediatric surgeons avoid proactively after PSARP because of its risk of developing into megarectum which eventually presents as chronic fecal impaction and pseudoincontinence.

62.5% (10 out of 16) patients with fistula complained of less than 3 bowel movements per week, while in patients without fistula the same was reported by 60% (9 out of 15) patients.

Hard lumpy stools were reported by 25% (4 out of 16) patients with fistula and 53.3% (8 out of 15) patients without fistula.

31.25% (5 out of 16) patients with fistula and 20% (3 out of 15) patients without fistula complained of loose stools.

37.5% (6 out of 16) patients with fistula and 40% (6 out of 15) patients without fistula had fecal impaction on examination in follow-up visits.

The p-value was >0.05 in digital rectal examination results, number of bowel movements, types of stool and frequency of soiling showing that there is no statistically significant correlation between outcome and presence or absence of fistula.

After surpassing the exclusion criteria patients included in this study were only intermediate type with or without fistula; cases of very high imperforate anus or poor muscles and an abnormal sacrum were excluded.

$p=1.0$, thus showing that there is no significant correlation between normal DRE and patient being clean in between bowel movements.

In an earlier study about 50% of patients soiled their underwear occasionally post PSARP.³⁷ In our study 29% (9 out of 31) patients had grade 1 (once a week) soiling, 29% (9 out of 31) patients complained of grade 2 (once a day, without social problems) soiling.

40% of patients in the same reference study reported voluntary bowel movements without a single soiling episode post PSARP, thus making them totally continent³⁶ In our study 42% (13 out of 31) patients reported being completely clean in

between bowel movements, without a single soiling episode.

While Pena and Levitt found 25% patients suffer from faecal incontinence³⁷ and must receive a bowel management regimen to artificially keep them clean our study did not have any patients complaining of grade 3 incontinence. Although 19.35% (6 out of 31) patients reported more than 3 bowel movements per day, 25.8% (8 out of 31) patients complained of loose stools and 29% (9 out of 31) patients complained of grade 2 incontinence, all 3 complaints together were present only in 4 (13%) patients. Also episodes of soiling are usually related to constipation, and when constipation is treated properly, the soiling frequently disappears.

Patients with real incontinence require a bowel management program, which involves cleaning of the child's colon once a day by the use of a suppository, an enema or a colonic irrigation.³⁸

Even after the child has achieved continence it is important to look out for constipation and faecal impaction to avoid pseudoincontinence.

p-value is >0.05, shows that there is no significant correlation in presence and absence of fistula with occurrence of anal excoriation, anal stenosis and presence of faecal matter on anal inspection in the patients of ARM.

Statistically significant relationships ($p=0.006$) was seen in anal excoriation among patients with loose stools and anal excoriation among patients with more than 3 bowel movements per day. On the other hand, there was no significant relationship between grade 2 incontinence and anal excoriation ($p=0.059$); decreased pressure on DRE (digital rectal examination) and anal excoriation ($p=0.107$).

In our study, the quality of life regarding functional outcome was difficult to determine, because of short duration of follow-up. Our findings based on interviewing mothers regarding quality of life in terms of physical growth, bowel movement and continence were satisfactory. Rintala et al in their follow-up assessment of post-operative functional outcome of 208 patients revealed that acceptable toilet training and bowel control for age were achieved after PSARP.³⁹

Neonatal repair of anorectal malformation had been advised by Albanese et al., who advocated that early restoration of gut continuity in this deformity would train the pelvic musculature early and then better functional outcome on the long run. Better rectal dissection and tapering if needed is noticed in neonatal PSARP due to the absence of pouchitis and fibrosis noticed in a long-term unused rectal pouch in delayed repair.⁴⁰ The early complication rate in our centre is 24.24%, which is, comparable to 26% quoted by Nakayama et al.³⁴ This includes superficial wound infections that healed spontaneously on regular change of dressing. p-value is >0.05, thus showing that there is no significant difference in early post operative findings among with fistula and without fistula.

Most complications following the PSARP are said to be preventable, with attention to careful selection of patients, vigilant postoperative wound care and anticipating complications. Rectal prolapse occurred in one of our patients, but did not require excision.

PSARP avoids multiple admissions and surgeries, shortens duration of hospitalization and reduces the overall cost of treatment which is a relief in a setting where the majority of parents belonged to the low socioeconomic class.

Conclusion

By adopting Wingspread classification and locally adapted inclusion criteria, 33 children with intermediate type ARM (17

with fistula and 16 without fistula) out of 52, underwent primary PSARP in the tertiary care setting. Late presentation of clinically compromised babies was a major exclusion criterion which emphasizes the need for early referral of children with ARM.

All patients were operated within 1 to 5 days of life. In our study, the quality of life regarding functional outcome was difficult to determine, because of short duration of follow-up. Our findings based on interviewing mothers regarding quality of life in terms of physical growth, bowel movement and continence were satisfactory.

Out of 33 operated intermediate type of ARM cases 1 patient without fistula succumbed to fatal septicemia and 1 patient with fistula was lost to follow-up after being discharged.

Most frequent functional disorder encountered after PSARP in patients with and without fistula was constipation (61.3%) 19 out of 31.

No statistical significant difference between with fistula and without fistula was seen on digital rectal examination results, number of bowel movements and types of stool.

42% (13 out of 31) patients reported being completely clean in between bowel movements at end of follow-up. No statistically significant correlation was found between normal DRE and patient being clean in between bowel movements.

29% (9 out of 31) patients reported grade 2 incontinence (soiling once a day) which completely resolved with toilet training and dietary management over course of one year follow-up. None of the patients reported being incapacitated by incontinence.

There was significant relationship in anal excoriation among patients with loose stools and with more than 3 bowel movements per day.

In conclusion, the PSARP is a useful procedure for the correction of ARM in children in developing countries and quality of life depends on clinical status of patient and age at the time of presentation. No significant statistical differences in quality of life was seen in patients with fistula vs patients without fistula post PSARP.

Limitations

In spite of some positive outcomes, our study had certain limitations-

- Due to small sample size the outcome cannot be considered accurate.
- Secondly, the small duration of our study with lack of adequate follow up data further weakened our outcome.

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