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Comparison between conservative and surgical management in postpartum pubic symphysis diastasis: a randomized controlled trial

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ABSTRACT

Background: Pubic symphysis diastasis is a postpartum complication with an incidence of 1:385 to 1:500 births. Typically conservative treatment is performed, operative treatment is also successful alternative method. This study was conducted to assess whether surgery (ORIF) provide early pain relief and improve mobility and quality of life than conservative management does in same patients.
Methods: This study is a randomized controlled trial conducted at MKCG Medical College, Berhampur from December 2014 to April 2017. Total eligible 16 postpartum pubic diastasis patients coming to MKCG hospital were randomly assigned to two groups in 1:1 ratio. Group A received surgical and group B conservative management. All were followed up at 3 weeks, 6 weeks, 3 months and upto 6 months in which EQ-5D-3L score and Visual analogue scale were measured for assessing pain and general health outcome in participants. All data were analyzed with SPSS.
Results: The mean EQ-5D descriptive index was almost similar in both groups at the time of admission, but declined more rapidly in group A as compared to that in group B. 75% of group A has this index 5 (lowest score) at 6 months whereas none of the group B patients attained it. lower EQ-5D index indicates patients had good mobility and early ambulation, less discomfort, able to do usual activity. There was a significant difference in mean EQ-5D descriptive index and pain VAS score between two groups.
Conclusions: This study showed surgical management is more effective than conservative management in postpartum pubic symphysis patients by rapidly improving general health, ameliorating pain and bringing ambulation.

Keywords: Pubic symphysis diastasis, RCT, EQ-5D score, ORIF

INTRODUCTION

Postpartum pubic symphysis diastasis was earlier assumed to be an uncommon complication with a varying incidence of 1:300 to 1:30,000 due to inconsistent reporting.[1] However, more recent studies suggest that this condition is more common with an incidence between 1:385 and 1:500 births.[2,3] The pubic symphysis is normally 4 to 5 mm in size and undergoes a 2 mm to 3 mm increase during pregnancy.[4] The etiology of peripartum diastasis of the pubic symphysis without a history of trauma is unknown; but this is associated with underlying connective tissue disorders, cephalopelvic disproportion and macrosomia.[5] Improper management can lead to significant functional disability and chronic pain.[2,5,6] Clinical diagnosis can be confirmed rapidly by pelvic X-ray and CT scan. Additionally, MRI can exclude soft tissue injury. However, there is no consensus on the optimal therapy. Typically a conservative treatment is performed comprising pelvic binder, analgesia, bed rest in lateral decubitus position and physical therapy.[1,3,5,7-16] In several cases it has been reported that in cases with extreme pubic symphyseal rupture having pelvic instability or persistent pain after conservative therapy, operative treatment is a successful alternative method.[3,17-19] So this study was planned to

assess whether surgery (open reduction and internal fixation (ORIF)) provide early pain relief and bring improvement in mobility and quality of life than the usual conservative management does in patients with pubic symphysis diastasis.

The aim of this randomized controlled study is to compare the effectiveness of the surgical management (ORIF) over the standard practice (conservative management) for postpartum pubic diastasis. The pain, ambulation and general health outcome of participants which were measured by EQ-5D score and Pain VAS score during follow up were the main outcomes for this. Our null hypothesis is that there is no difference in the time of pain resolution and the return of pain-free ambulation (no difference in EQ-5D score and pain VAS score) between patients receiving conservative management and surgical management.

METHODS

Study design and participants

The present study is a randomized controlled trial (parallel trial) conducted at MKCG Medical College, Berhampur from December 2014 to April 2017. Prior to the study ethical approval has been obtained from the ethical committee of MKCG Medical College. Patients with postpartum pubic diastasis coming to MKCG hospital within the study period were enrolled for the study.

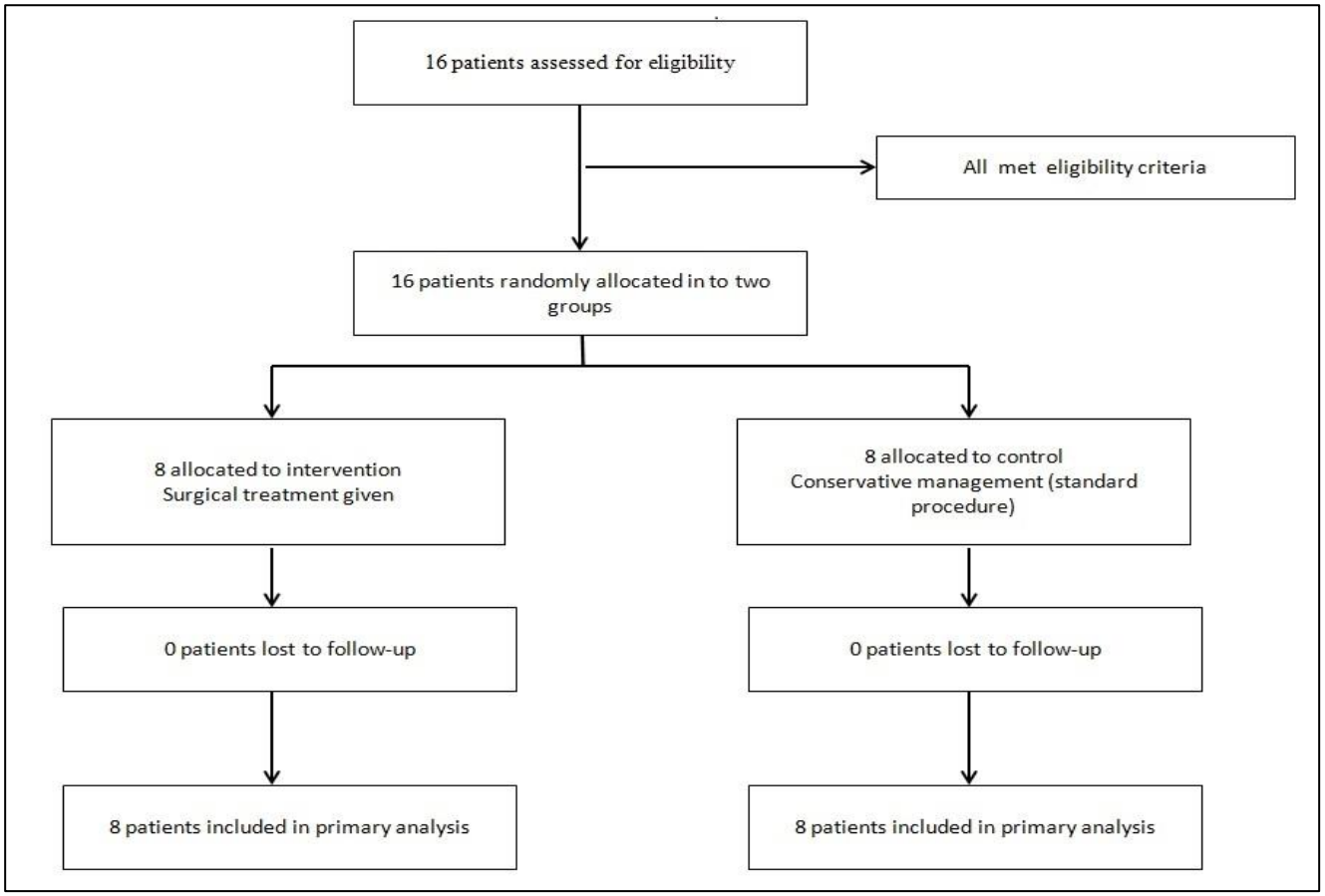

Figure 1: Flow diagram showing enrollment, intervention, follow-up and analysis in the study (modified from the CONSORT 2010 flow diagram).

Patients in the age group of 20 to 40 years and with postpartum pubic diastasis of more than 5 cms gap were included and patients with a history of pelvic trauma, connective tissue disorder, Cushing disease and hypoparathyroidism, an extreme symphyseal rupture with pelvic instability and cases more than 2 weeks old were excluded. Assuming a minimal 2 score improvement in the EQ-5D descriptive index, standard deviation as 3 and mean index in the treatment group as 8 and in control group as 10, the sample size was calculated to be 20 to achieve 90% power at 5% level of significance. In our study total 16 eligible patients were enrolled during the study period.

Methodology

The patients were randomly assigned to two groups in 1:1 ratio. Group A (intervention group) consists of 8 patients who received surgical management and group B (control group) of 8 patients who received a standard procedure

that is conservative management. Due to the nature of intervention masking of patients was not possible. Informed consent was obtained from patients prior to the study. All participants were provided with a patient information sheet and had an opportunity for discussion with a principal investigator at their first orthopaedic attendance.

Intervention

In the study, the intervention was surgical management (ORIF). For the procedure, Pfannenstiel approach was done under spinal anaesthesia in the supine position, reduction of symphysis pubis was done and fixed with 3.5 reconstruction plate and 3.5 cortical screws. A suction drain was given and the wound was closed in layers. Standard postoperative rehabilitation protocol maintained. Stitches were removed on the 12th day. Pelvic exercises were started from 2nd postoperative day. Partial weight bearing given on 3rd postoperative day with help of walker. Serial radiographs were obtained immediately after the operation, at 3 weeks, at 6 weeks and at 3 months of follow up. Conservative management was done in form of analgesics (NSAIDS and Opioids), bed rest, pelvic binder and physical therapy. Patients were given pelvic binder and analgesics as per requirement. Physical therapy was implemented to all patients. All the patients were gradually mobilized according to their pain tolerance with the help of a walker and subsequently to walking stick after 3weeks or even more in some cases. All patients in both groups were followed up at 3 weeks, 6 weeks, 3 months and 6 months of their management. At the time of admission to the hospital all patients were assessed in form of routine blood investigation, X-ray of the pelvis with both hip- AP inlet and outlet views and CT SCAN of the pelvis. A thorough clinical examination was done.

Outcome measurement

The general health outcome, pain and ambulation in patients were the primary outcomes in the study. The variables were measured with help of EuroQol Group 5-Dimension self-report questionnaire 3 level version (EQ-5D-3L) at each follow-up visit. This tool is used worldwide. It includes an EQ-5D descriptive index and EQ visual analogue scale (EQ VAS). EQ descriptive index consists of 5 dimensions like mobility, self-care, usual activities, pain/discomfort, anxiety/depression. It ranges from 5 to 15 and a lower score indicates better general health outcome and pain relief. EQ VAS score records self-rated health state in people. Its score ranges from 0 to 100 where 0 is worst imaginable health state and 100 is best imaginable health state.[20]. For recording pain in patients, Visual analogue scale (VAS) was used which ranges from 0 to 100. Pain VAS score 0-4 means no pain, 5-44 means mild, 45-74 is moderate and 75-100 indicates severe pain. Reliability of this tool is good and validity is high (correlation ranges from 0.62-0.91 for numeric rating scale).[21] In the study, this score was obtained with face to face interview by an investigator who was blinded to reduce bias.

Statistical analysis

All data were analyzed with SPSS (version 16). To reduce bias during interpretation randomization code was broken before analysis. To assess the superiority, mean of scores between two groups analyzed. As variables were continuous data and not normally distributed across participants, nonparametric test (Mann-Whitney test) was applied to compare the means of outcomes in the two groups. In the study P value less than 0.05 was taken as statistical significant.

RESULTS

A total 16 patients underwent randomization (Figure 1), 50% assigned to surgical treatment group (A) and 50% to the conservative treatment group (B). All participants were followed up to the end of follow up period and loss of follow up was nil. None of the patients of group A had implant failure. Perioperative and postoperative were uneventful. Baseline characteristics of all participants were depicted in Table 1**.**

Table 1: Baseline characteristics of all participants (N=16).

Characteristics	Group A (N= 8) (Surgical treatment)	Group B (N=8) (Conservative management)
Age [n (%)]		
20-30 years	6 (75%)	7 (87.5%)
31-40 years	2 (25%)	1 (12.5%)
Religion		
Hindu	8 (100%)	8 (100%)
Others	0	0
Marital status		
Married	8 (100%)	8 (100%)
Unmarried/divorcee	0	0
Occupation		
Working	2 (25%)	3 (37.5%)
Not working	6 (75%)	5 (62.5%)
Education		
Illiterate	1	0
Primary	4	4
Middle school	2	1
Graduation and above	1	3
EQ-5D score at time of admission		
EQ-5D descriptive index	14.5	14.1
EQ VAS score	16.7	18.2
Pain VAS index	90	90

EQ-5D score and pain VAS score of each study participants at the time of admission, 3 weeks, 6 weeks, 3 months, 6 months were described in Table 2 and 3.

6 out of 8 patients in group A had EQ-5D score 5 at 6 months of follow up but no one in group B attained EQ-5D score 5 at the same time. The suprapubic pain was present in all patients of group B and 1 patient of group A at end of follow up. The comparative analysis of EQ-5D score and Pain VAS score between patients with conservative management and with surgical management were elucidated in Table 4.

Table 2: EQ 5D score (EQ-5D descriptive index and EQ VAS score) of study participants at the time of admission, 3 weeks, 6 weeks, 3 months, 6 months of follow up period (N=16).

Score at time of follow up		EQ-5D descriptive index					EQ VAS score				
		At time of admission	At 3 wks	At 6 wks	At 3 months	At 6 months	At time of admission	At 3 wks	At 6 wks	At 3 months	At 6 months
Group A	1	15	11	9	6	5	10	40	56	76	98
	2	14	11	8	6	5	15	42	60	78	94
	3	15	12	8	7	6	22	38	50	65	86
	4	15	10	8	6	5	13	40	64	71	91
	5	14	11	8	6	5	27	39	69	76	88
	6	13	11	8	6	5	11	41	55	72	94
	7	15	9	9	7	5	15	42	59	70	92
	8	15	10	8	7	6	21	37	48	62	83
	Mean ±SD	**14.5 ±0.7**	**10.6 ±0.9**	**8.3 ±0.5**	**6.3 ±0.5**	**5.3 ±0.5**	**16.7 ±5.9**	**39.8 ±1.8**	**57.6 ±6.9**	**71.3 ±5.6**	**90.7 ±4.8**
Group B	1	14	13	10	8	6	11	23	50	67	76
	2	15	14	11	9	7	15	20	60	70	83
	3	14	12	10	9	7	28	38	46	54	60
	4	14	13	10	7	6	10	26	58	64	74
	5	15	13	11	9	8	27	32	60	70	84
	6	13	12	9	7	6	9	18	55	63	79
	7	13	11	8	6	6	20	30	54	67	76
	8	15	13	11	8	7	26	36	50	58	70
	Mean ±SD	**14.1 ±0.8**	**12.6 ±0.9**	**10 ±1**	**7.9 ±1.1**	**6.6 ±0.7**	**18.2 ±8**	**27.9 ±7.3**	**54.1 ±5.1**	**64.1 ±5.7**	**75.3 ±7.7**

Table 3: Pain VAS score of study participants at the time of admission, 3 weeks, 6 weeks, 3 months, 6 months of follow up period (N=16).

Score at the time of follow up		At time of admission	At 3 wks	At 6 wks	At 3 months	At 6 months
Group A participants	1	96	70	45	5	0
	2	87	68	41	2	1
	3	99	77	50	10	7
	4	82	59	36	1	0
	5	90	70	39	2	0
	6	88	69	37	2	0
	7	93	57	40	3	0
	8	85	61	35	2	1
	Mean±SD	**90±5.7**	**66.3±6.7**	**40.3±5**	**3.4±2.9**	**1.1±2.4**
Group B participants	1	95	87	60	49	28
	2	88	75	56	43	25
	3	97	89	62	50	30
	4	85	73	54	44	26
	5	91	77	55	45	25
	6	85	73	52	43	22
	7	92	84	59	50	28
	8	87	74	55	42	24
	Mean±SD	**90±4.5**	**79±6.6**	**56.6±3.4**	**45.8±3.4**	**26±2.5**

Table 4: Comparison of EQ-5D score and pain VAS score between patients with conservative management and patients with surgical management (N=16).

Score at follow up time	Group A (Mean±SD)	Group B (Mean±SD)	P value
EQ-5D score			
At time of admission	14.5±0.75	14.1±0.83	0.382
At 3 weeks of follow up	10.62±0.91	12.6±0.91	0.002*
At 6 weeks of follow up	8.25±0.46	10±1.06	0.005*
At 3 months of follow up	6.37±0.51	7.8±1.12	0.010*
At 6 months of follow-up	5.25±0.46	6.62±0.74	0.002*
Pain VAS score			
At time of admission	90±5.7	90±4.5	1.000
At 3 weeks of follow up	66.37±6.7	79±6.61	0.002*
At 6 weeks of follow up	40.37±5.01	56.6±3.37	0.000*
At 3 months of follow up	3.37±2.92	45.7±3.37	0.000*
At 6 months of follow up	1.12±2.41	26±2.56	0.000*

*statistical significant as P value less than 0.05.

Figure 2: X-ray of pelvis of a 22-year-old female. A- Preoperatively, B- Postoperatively.

Figure 3: X-ray of pelvis of a 40 years old female. A- Preoperatively, B- Postoperatively.

Radiographical image of patients at preoperative and 6 weeks postoperative period is shown in Figure 2 and 3.

DISCUSSION

The present study examined the effectiveness of surgical management over conservative management in patients with pubic symphysis diastasis. Our analysis showed that at the time of admission the mean EQ-5d descriptive index was almost similar in both group, but it declined more rapidly during follow up period in group A patients where ORIF was done as compared to that in group B patients where conservative management was employed. 75% of participants of group A has EQ-5D descriptive

index 5 (which is the lowest score) at 6 months of follow up. But none of the patients in group B patients attained it at the same follow-up period. A lower EQ-5D descriptive index in group A patients indicates patients had good mobility and early ambulation, less discomfort, less pain, were able to do self-care and daily activity. But group B participants had persistent pain, low mobility and face difficulty in doing usual activities at 6 months of follow up. Similarly, mean EQ VAS score was higher in group A than that in group B which indicates patients receiving ORIF had better health state than patients with conservative management. Mean EQ-5D index in group B remained higher than that in group A throughout the follow-up period and this difference was significant in each follow-up visit.

Similarly, pain VAS score was same in both the groups at the time of admission. But with the follow-up time mean pain VAS score declined drastically in group A where as in group B it was slower. At the end of follow-up period mean VAS score in group A was below 4 (means no pain) where as in group B it was 26±2.5 (score between 5-44 means mild pain). 1 patient in group A and all patients in group B had persistent suprapubic pain at the end of the follow-up period. The difference in the mean VAS score between two groups' patients was statistically significant at each follow-up time. So at the end this study illustrated that early surgical consideration and intervention for postpartum diastasis of the pubic symphysis can result in improved outcome including improved pain management and return to ambulation. When surgical management is implemented, it likely to decreases the recovery time and improve overall functional outcome.

Kharrazi et al has reported patients with conservative management had persistent posterior pelvic pain after 2 years and suggested consideration of operative approach for these cases.[22] Incomplete recovery from pain in case of conservative management was also found by Rommens et al in their case reort.[6] Dunivan et al stated that aggressive treatment of severe pubis symphysis separation with external fixation results in early ability to ambulate and care for self.[23] Graf et al in the case report

illustrated that patient was able to ambulate without complaints after 2 weeks of ORIF of pubic symphysis separation of 60 mm.[24] Snow et al, Rommens et al, Dunivan et al opined that pubic symphysis gap more than 4 cm is an indication for operative plate fixation.[1,6,23]

In contrast, many articles have shown that conservative therapy is a reasonable approach.[1,7,15,25,26] Joosoph et al observed that a patient with 45 mm pubic symphysis gap was able to walk independently with a walking stick and no longer felt pain after 1 month of conservative management. However, 20 mm separation was still there. At 7 months and 3 years after her delivery, her X ray showed that 20 mm gap persisted, however she remained well.[7] The effectiveness of conservative management approach was also found by Senechal et al and Dunbar et al in their studies.[25,26] Good results reported even with diastasis measuring 9 cm associated with sacroiliac joint by Idrees et al and 5 cm gap by Culligan et al.[8,27] Cowling et al found successful outcome by conservative management in a case of 9.5 cm diastasis.[28]

Limitations of the study

Possible bias due to self-reported score value may be a possible bias, although we recorded no evidence for bias caused by this. If participants could be followed up for more periods, a better result could be obtained. However, the desired effect of the intervention was almost achieved in the intervention group within the follow-up period.

CONCLUSION

This study showed that surgical management is more effective than conservative management in postpartum pubic symphysis patients by rapidly improving general health, ameliorating pain and bringing ambulation. This study shows that early orthopaedic consultation and surgical consideration can improve outcomes when symphyseal separations are greater than 5 cm where conservative management has been frequently employed. Delay in surgical intervention has short and long-term risks which may be compounded by partial healing and increased surgical complexity. When surgical management is implemented, it is likely to decrease recovery time and improve overall functional outcome. Post-Partum Pubic diastasis, which is many times overlooked by the obstetricians and orthopaedic surgeons, is a disabling condition requires prompt and rightful intervention.

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