Open Peer Review on Qeios

A Study to Assess the Effectiveness of Pelvic Floor Muscle Strengthening Exercises on Erectile Dysfunction in Rectal Cancer Survivors at Tertiary Cancer Hospital, TMH, Homi Bhabha National Institute, Mumbai

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Abstract

Objectives: A study to assess the effectiveness of pelvic floor muscle strengthening exercises on erectile dysfunction in rectal cancer survivors at tertiary cancer hospital, TMH, Mumbai.

Methodology: Single arm prospective study approach was used for the study. The research design was self-controlled trial design. Sample size were 39 participants who received an intervention of pelvic floor muscle strengthening exercises in the selected areas of Tata Memorial Hospital. Data gathered was analyzed using descriptive and inferential statistics.

Participants had filled SHIM questionnaire pre intervention. Questionnaire had 5 different questions in terms of Confidence, erection, penetration, difficulty and satisfaction. Patients had been taught Pelvic floor muscle strengthening exercises on Day 0, which were asked to carry out 3 times a day for a period of 10 weeks. Assessment was done at the end of 10 weeks.

Results of the studies: In pre-intervention SHIM questionnaire, Mean score and Standard Deviation among 5 questions were Confidence (2.6154±0.5901), Erection (2.5128±0.6014), Penetration (2.1764±0.3888), Difficulty(2.2564±0.5964) and satisfaction(2.2821±0.5595). In Post intervention SHIM score among 5 questions were Confidence (3.0513±0.6047), Erection(2.8974±0.6804), Penetration(2.3590±0.6277), Difficulty(2.3590±0.6277) and satisfaction(2.6410±0.6684) The confidence, erection, satisfaction post intervention were statistically highly significant in participants (P< 0.001) and in term of Difficulty it was statistically significant (P 0.005).

The Wilcoxon signed rank test explained that there was a significant increase in the scores of confidence (4.123), erection (3.873) and satisfaction (3.500). They were highly statistically significant (P< 0.001).

There was a significant increase seen in the scores of penetration (4.123) and difficulty (3.873). They were statistically significant (p 0.001 and 0.046) respectively. Hence the pelvic floor muscle strengthening exercises were helpful in improving erectile dysfunction among rectal cancer survivors.

Conclusion: It could be concluded that null hypothesis H0 is rejected and H1 hypothesis of Pelvic floor muscle strengthening exercises has helped to improve erectile dysfunction among men. Limitation being since study time was for 10 weeks only, the results for better outcome in terms of penetration and difficulty can have continuous exercises and then follow up.

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Introduction

The rectum is the last part of the large intestine and connects the sigmoid colon to the anal canal. It's upper third lies intraperitoneally, middle third retroperitoneal and lower third under the pelvic diaphragm[1]. The pelvic autonomic nerves, superior hypogastric plexus, and inferior hypogastric connect to the ureters and inferior hypogastric plexus runs to the bladder and sexual organs where they are in close contact with the anterior wall of the rectum[1]. Erection of the penis is by five main phases: initial filling, partial erection, full erection, rigid erection, and return to a flaccid state. The dorsal nerve, a branch of the pudendal nerve gives primary innervation. The cavernosal nerves and the dorsal somatic nerves are responsible for penile sensation[6].

Every year 145,000 new cases are registered of which one-third is in the account of rectal cancers. Colorectal cancer is estimated to be the fourth most commonly diagnosed cancer in U.S. men and women of age 30 to 39 are affected more [16]. Rectal cancer will attribute to 52,980 deaths this year. Rectal cancer is the second leading cause of cancer death in the United States [1]. 95 percent of rectal cancers are adenocarcinomas[1]. Less common types of colorectal cancer include primary colorectal lymphomas, stromal tumors and leiomyosarcomas. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program states 4.1 percent of people may develop rectal cancer during their life.

Surgery is usually the main treatment for rectal cancer. Radiation and chemotherapy are often given as adjuvant or neo adjuvant. The type of surgery depends on the stage of cancer. Low anterior resection (LAR), is done in stage I rectal cancers and most stage II or III cancers in the upper part of the rectum. Abdominoperineal resection (APR) is to treat stage I cancers and many stage II or III cancers in the lower part of the rectum. It's often needed if the cancer is in the anal sphincter muscle or the nearby levator ani muscles responsible for sexual functioning can cause erectile dysfunction which is underdiagnosed and undertreated. The sympathetic nerves are at risk during presacral and ventrolateral dissection of the mesorectum and central arterial ligation and the parasympathetic nerve supply is especially at risk during deep dissection of the lateral planes. Low rectal cancer increases the risk of combined damage to the pelvic splanchnic nerves and levator ani nerves, due to the small surgical margin deep in the pelvis.[37]

Pelvic floor exercises are very effective in treating erectile dysfunction. The Ischiocavernous and bulbocavernosus muscles are superficial pelvic floor muscles that are active during erection and which enhance rigidity. The bulbocavernosus muscle encircles 33–50% of the base of the penis and prevents blood from escaping and exerts pressure on the deep dorsal vein, pumps during ejaculation, and empties the bulbar urethra[23]. Erectile dysfunction in rectal cancer operated patients specially low anterior resection, is common due to surgical interventions and involvement of pelvic nerves. Even in nerve- sparing surgeries handling of nerves also gives incidences of erectile dysfunction. Dysfunctions in the pelvic floor musculature often occur due to a lack of activation, control or strength. Reduction in tone and alterations in contractile patterns have been linked to incontinence and may directly impact erectile strength and the ejaculatory process states Gokce Ayelin [41]. Investigator would like to understand the role of strengthening of the pelvic muscles in improving erectile dysfunction. An overview states that various exercises of pelvic floor, aerobics have a role in improving erectile dysfunction. But the role of yoga in combination with pelvic floor exercises which are simple with no financial implications were not studied.

Criteria of selection of sample

Inclusion criteria:

- Age> 18 years and < 65 years of rectal cancer patients. Gender- Male Patients.
- Patients who had undergone rectal surgeries such as AnteriorResection (AR), Abdomino- Perineal Resection (APR), Inter Sphincteric Resection (ISR).
- Post surgery follow up patients after 6 months. Patients who can perform exercises.
- Patient who can read, write and speak English.

Exclusion criteria:

Patients with previous history of erectile dysfunction prior to treatment. Extended total mesorectal excision patients, Patients with neurological problems such as Cerebro-vascular Accidents, multiple sclerosis, spinal cord injury or Parkinson’s disease.

Data collection tool

SHIM Questionnaire:

The SHIM is intended to serve as a screening and diagnostic aid and to complement, not suppliant, clinical judgment. The SHIM is intended to enhance the decision making of clinicians who are likely to perform more detailed evaluations in individual cases.

Number of items: 5

Question items:

1. Confidence of Erection 2.Erection hard enough for penetration 3. Maintainance of erection during sexual intercourse 4. Difficulty in maintaining erection during sexual intercourse. 5. Satisfaction Interpretation- 22-25 -No ED, 17-21 -Mild ED, 12-16 -Mild-to-moderate ED, 8-11 -Moderate ED 1-7 -Severe ED.

Intervention carried out

Pelvic Floor Muscle Strengthening Exercises:

Total time required for 3 Pelvic Floor Exercises- 4 min

1. Kegel exercises.
2. Supine leg raises.
3. Pelvic curl/ bridge.

Total time required for 3 yoga asanas-8 min

1. Paschimottasana (Forward Bend Pose).
2. Baddhakonasanas (Bound Angle Pose).
3. Virbhadra Asanas 3 (warrior pose 3).
4. Kegel exercises for men
5. Pilates exercises- supine leg raises
6. Pelvic curl/ bridge
   Paschmottanasanas – forward bend pose
   Baddha konasana
   Virbhadra asanas3 (warrior pose 3)

Data Analysis and Interpretation

Section I Part – A

46.2% belonged to age group of 36-45. (table 1). 94.9% were married (table 2). 49% had 2 children. 79.5% had undergone anterior resection and 20.5% had APR (table 4). 33.4% had CAPOX/FOLFOX, FOLFIRINOX and adjuvant radiotherapy were followed by 2.6%respectively. Neoadjuvant RT were followed by 87.2%. 79.4% received >50gy RT. 59% were in stage III (table 8). 2.6% had diabetes and hypertension respectively.

Section II A

Comparison of participants according to the type of erectile dysfunction in pre- intervention and post-intervention rectal cancer participants using SHIM questionnaire. (table 10) showed

In pre-intervention program, 0% participants had no erectile dysfunction (22-25), 2.6% participant had mild erectile dysfunction (17-21), 48.7% participants had mild to moderate erectile dysfunction (12-16), 48.7% participants had moderate erectile dysfunction (8-11) and 0% participants had severe erectile dysfunction (22- 25).

In post-intervention program, 0% participants had no erectile dysfunction (22-25), 7.7% participant had mild erectile dysfunction (17-21), 71.8% participants had mild to moderate erectile dysfunction (12-16), 20.5% participants had moderate erectile dysfunction (8-11) and 0% participants had severe erectile dysfunction (22- 25).

The pelvic floor muscle strengthening exercises were found statistically significant in participants by Chi-square value was 7.205 and P value was 0.027.

*Statistically Significant at 5% level i.e., P<0.05

Section II B

Dealt with the effectiveness of pelvic floor muscle strengthening exercise.

In the pre-intervention SHIM questionnaire, the Mean score and Standard Deviation among 5 questions were Confidence (2.6154±0.5901), Erection (2.5128±0.6014), Penetration (2.1764±0.3888),

Difficulty (2.2564±0.5964) and satisfaction (2.2821±0.5595).

In Post intervention SHIM score among 5 questions were Confidence (3.0513±0.6047), Erection (2.8974±0.6804), Penetration (2.3590±0.6277), Difficulty (2.3590±0.6277) and satisfaction (2.6410±0.6684)

The confidence, erection, satisfaction post-intervention were statistically highly significant in participants (P< 0.001), and in terms of Difficulty, it was statistically significant (P 0.005).

The Wilcoxon signed-rank test explains that there was a significant increase seen in the scores of confidence (4.123), erection (3.873), and satisfaction (3.500). They were highly statistically significant (P< 0.001). There was a significant

increase seen in the scores of penetration (4.123) and difficulty (3.873). They were statistically significant (p 0.001 and 0.046) respectively.

*Statistically significant at 5% level i.e., P<0.05.

**Statistically highly Significant at 0.1% level i.e., P<0.001 Conclusion:

Hence the pelvic floor muscle strengthening exercises helped improve erectile dysfunction among rectal ca

This table shows that the Null Hypothesis (H0) was rejected and the Research hypothesis (H1) is accepted.

Section III

Table 12 dealt with the incidence of erectile dysfunction in rectal cancer survivors.

Among 39 participants, 0% participants had no erectile dysfunction (22-25), 2.6% participant had mild erectile dysfunction (17-21), 48.7% participants had mild to moderate erectile dysfunction (8-11), 48.7% participants had moderate erectile dysfunction and 0% participants had severe erectile dysfunction (22-25).

Last section dealt with association of clinical data with SHIM score. (table 13). No association with age, marital status, children, types of surgery, types of chemotherapy and RT status and TNM staging were seen.

Discussion

Erectile dysfunction in rectal cancer survivors appeared as a significant adverse effect due to surgery as well as radiation therapy.

Attaallah W (2018) carried out a prospective study in 187 rectal cancer patients in Turkey, 117 patients with radical resection in the pelvic cavity faced difficult sexual dysfunction post- surgery. In male patients, sexual dysfunction raised from 4% to 41% post-surgery. Advanced stage of disease and adjuvant chemotherapy had more percentage of sexual dysfunction in terms of erection. Sexual function was also a major indicator of the quality of life in male patients. This study explained that sexual dysfunction in rectal cancer patients after radical treatment is most common. ED has developed after surgery in 38% of the male patients. ED reported by only two (6%) of 30 patients who had laparoscopic rectal surgery, 50% of patients had undergone open surgery ($P < 0.001$). N2 stage nodal involvement has a higher rate of erectile dysfunction than N0 involvement. In our study the type of surgery, 79.5% of participants had undergone Anterior resection surgery and 20.5% participants had undergone Abdominoperineal resection. Neo adjuvant chemo radiation had erectile dysfunctions with more incidence in stage three rectal cancer.

According to Kim JY (2018) a randomized controlled trial with the home-based exercise program having unsupervised walking, stationary bike, or swimming for aerobic exercise, and resistance exercise DVDs, a pedometer, and an exercise log, The change in the QOL between the intervention and control groups was insignificant. However, QOL was

dramatically improved in the exercise group. Sub- domains of QOL, emotional well-being, and trial outcome index-physical/functional/rectal were improved in the exercise group. Post 12 week exercise, PA was significantly increased and the change significantly differed compared with the control group. He concluded that a home-based exercise program may improve the QOL and psychological health in rectal cancer survivors.

In this study, 10 weeks of exercises were carried out. Post 10 weeks exercises the confidence, erection, satisfaction post interventions were statistically highly significant in participants and in terms of Difficulty it was statistically significant. The pelvic floor muscle strengthening exercises were found statistically significant in participants.

Helena C in 2018 conducted a non-randomized controlled feasibility study in which the rehabilitation group received an 8-week, bi-weekly education and exercise program which also included exercise diaries and telephone coaching sessions. Feasibility measures, functional exercise capacity, muscle strength, physical activity levels, pelvic floor symptoms, anxiety and depression, health-related quality of life, and self-efficacy were measured at baseline, immediately post-intervention and at 6 months post- baseline and compared within and between groups. The consent rate of the intervention arm was 24%. Eighty-one percent of the intervention arm attended 16 scheduled sessions. 96% of patients of the intervention arm program had overall satisfaction. Functional exercise capacity, handgrip strength, bowel symptoms, physical activity levels, depression, and HRQoL was statistically significant in the intervention arm ($p < 0.05$) at immediately post-intervention (time 2) which remained improved at 6 months post- baseline (time 3) ($p < 0.05$) than the control arm.In this study, participants visiting follow-up OPD were shown Pelvic floor muscle strengthening exercises. Participants were assessed post 10 weeks in OPD for post-intervention Erectile dysfunction score. This study showed that pelvic floor muscle strengthening exercises improved erectile dysfunction.

Merilyn M in 2011 on Urinary and sexual dysfunction Postoperative sexual dysfunction mentioned it ranged from 10% to 50%. Duran et al noted a 17.8% decrease in the sexual function of men compared with the preoperational period after abdominoperineal resection and low anterior resection. Both erection and ejaculation were impaired significantly. In this study, that there was a significant increase seen in the scores of confidence, erection, and satisfaction. They were highly statistically significant. There was a significant increase seen in the scores of penetration and difficulty. They were statistically significant respectively. The confidence, erection, satisfaction post-intervention were statistically highly significant in participants, and in terms of difficulty, it was statistically significant.

The barrier/limitation related to this study was during the follow-up period due to the covid-19 situation patients were sometimes unable to contact and adherence to exercises was disturbed in between which was later established after frequent follow-up and phone calls.

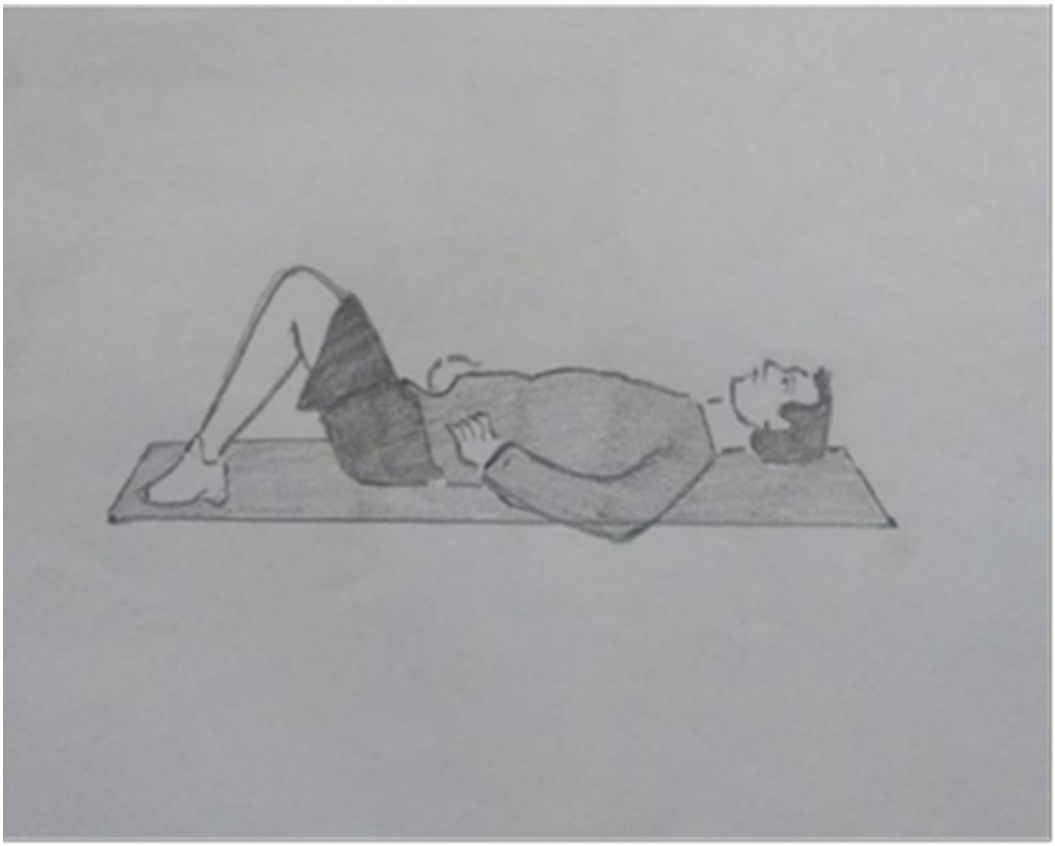
Conclusion

The strengthening of pelvic floor muscles have showed that moderate ED has reduced to mild ED with a duration of 10 weeks time period. A continual exercise with a longer period of follow up might still reduce the incidence of the grade of ED. This study proved the role of pelvic floor muscle strengthening exercise in improving erectile dysfunction.

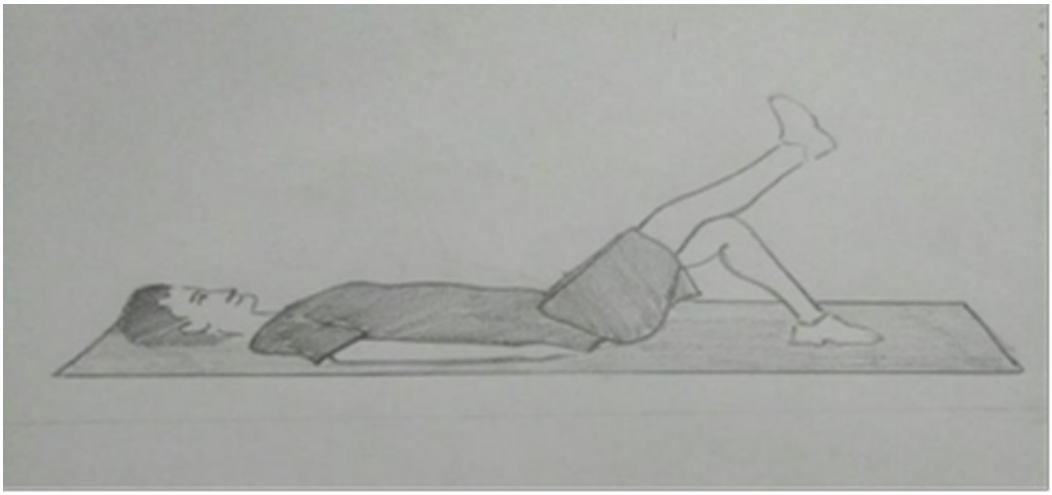
Scope of the study – This study will help in understanding that simple pelvic exercise which does not have any financial implication can overcome a major disturbance in men with colorectal cancers who have undergone surgery or adjuvant or neoadjuvant therapies. For the medical and nursing staff this study will help in counselling patients to overcome ED.

Figures and Tables

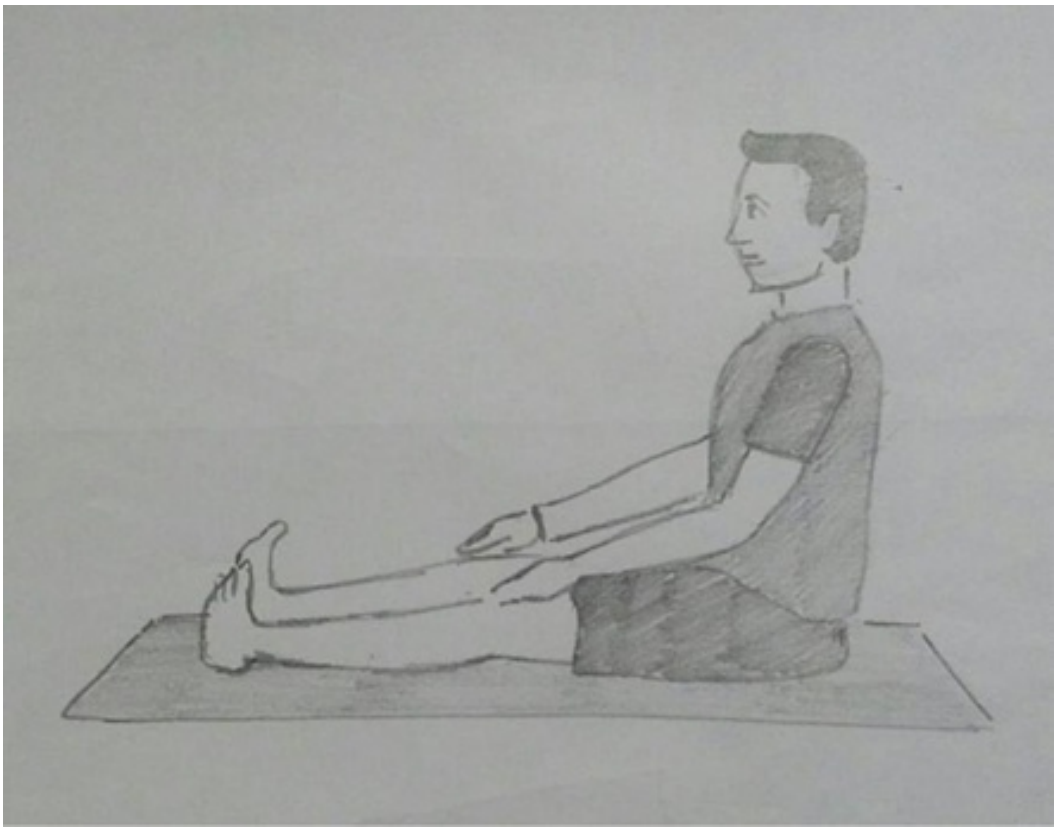
1. Kegel exercises for Men



2. Pilates Exercises-Supine leg raises



1. Paschimottanasanas (Forward Bend Pose)



1. Baddha Konasana

2. Virbhadra Asanas 3 (warrior pose 3)

Table I. DISTRIBUTION OF PARTICIPANTS ACCORDING TO AGE
(N=39)

Demographic variables	No. of Study participants	Percentage
Age Group (yrs)		
18 – 25	0	0.0
26 – 35	9	23.1
36 – 45	18	46.2
46 – 55	12	30.8
56 – 65	0	0.0
Total	39	100.0

Table II. DISTRIBUTION OF PARTICIPANTS ACCORDING TO MARIATAL STATUS
(N=39)

Demographic variables	No. of study participants	Percentage
Marital Status		
Unmarried	2	5.1
Married	37	94.9
Total	39	100

Table III. DISTRIBUTION OF PARTICIPANTS ACCORDING TO NUMBER OF CHILDREN
(N=39)

CLINICAL DATA	NO OF CHILDREN TO STUDY PARTICIPANTS	PERCENTAGE
	3	5%
	2	49%
	1	35%
	0	11%

Table IV. DISTRIBUTION OF PARTICIPANTS ACCORDING TO TYPE OF SURGERY
(N=39)

CLINICAL DATA	NO OF STUDY PARTICIPANTS	PERCENTAGE
Types of Surgery	No of participants	Percentage
Anterior Resection	31	79.5
Abdomino-Perineal resection	8	20.5

Table V. DISTRIBUTION OF PARTICIPANTS ACCORDING TO TYPE OF TYPE OF ADJUVANT THERAPY
(N=39)

CLINICAL DATA	NO OF STUDY PARTICIPANTS	PERCENTAGE
Adjuvant therapy	1	2.6
FOLFIRINOX	1	2.6
CAPOX/ FOLFOX/	13	33.4
Total	14	36

Table VI. DISTRIBUTION OF PARTICIPANTS ACCORDING TO RADIATION THERAPY
(N=39)

RADIATION THERAPY	NO Of STUDY PARTICIPANTS	PERCENTAGE
NACTRT	34	87.2
Nil	5	12.8
Total	39	100

Table VII. DISTRIBUTION OF PARTICIPANTS ACCORDING TO DOSE OF RADIATION THERAPY
(N=39)

DOSE OF RADIATION THERAPY	NO OF CHILREN TO STUDY PARTICIPANTS	PERCENTAGE
Dose of Radiation therapy		
<50GY/ 25#	7	20.6
≥50GY/ 25#	27	79.4

Table VIII. DISTRIBUTION OF PARTICIPANTS ACCORDING TO TNM STAGING
(N=39)

TNM STAGE	NO OF CHILDREN TO STUDY PARTICIPANTS	PERCENTAGE
Stage-1 (T1N0M0/T2N0M0)	7	17.9
Stage-2 (T3N0M0/T4N0M0)	8	20.5
Stage-3 (T1-4 N1-2 M0)	23	59.0
Stage-4 (T1-4 N 1-2 M1/2)	1	2.6
Total	39	100.0

Table IX. DISTRIBUTION OF PARTICIPANTS ACCORDING TO COMORBIDITY
(N=39)

CO-MORBIDITY	NO OF CHILDREN TO STUDY PARTICIPANTS	PERCENTAGE
Diabetes	1	2.6
Hypertension	1	2.6

Table X. COMPARISON OF PARTICIPANTS ACCORDING TO SEVERITY OF ERECTILE DYSFUNCTION IN PRE-INTERVENTION AND POST-INTERVENTION PATIENTS.

Intervention	SHIM Score											
	No ED (22-25)		Mil ED (17 – 21)		Mild ED (17 – 21)		Moderate ED (17 – 21)		Severe ED (1 –7)		Total	
	F	F	F	%	F	%	F	%	F	%	F	%
Pre Intervention	0	1	1	48.7	19	48.7	19	48.7	0	0.0	39	100.0
Post Intervention	0	3	3	20.5	28	71.8	8	20.5	0	0.0	39	100.0
Chi-square Test	7.205*											
P-Value	0.027											
Sig. at 5% level	Yes											

Table XI. ANALYSIS OF PELVIC FLOOR MUSCLE STRENGTHENING EXERCISES ON ERECTILE DYSFUNCTION SHIM SCORE IN PRE-TEST VS POST-TEST
(N=39)

Parameter	Pre Intervention		At 10 weeks		Wilcoxon Signed rank test	P-Value	Sig. at 5% level
	Mean±SD	Median	Mean±SD	Median			
Confidence	2.6154±0.5901	3.0	3.0513±0.6047	3.0	4.123**	<0.001	Yes
Erection	2.5128±0.6014	2.0	2.8974±0.6804	3.0	3.873**	<0.001	Yes
Penetration	2.1764±0.3888	2.0	2.4872±0.5559	2.0	3.464*	0.001	Yes
Difficulty	2.2564±0.5964	2.0	2.3590±0.6277	2.0	2.000*	0.046	Yes
Satisfaction	2.2821±0.5595	2.0	2.6410±0.6684	3.0	3.500**	<0.001	Yes
Total Score	11.8462±1.9539	12.0	13.4359±2.3708	1300	4.437**	<0.001	Yes

Table XII. INCIDENCE OF ERECTILE DYSFUNCTION IN PRE-INTERVENTION AND POST-INTERVENTION RECTAL CANCER PARTICIPANTS USING SHIM QUESTIONNAIRE
(N=39)

Intervention	SHIM Score											
	No ED (22 – 25)		Mild ED (17 – 21)		Mild to Moderate ED (12 – 16)		Moderate ED (8 – 11)		Severe ED (1 – 7)		Total	
	F	%	F	%	F	%	F	%	F	%	F	%
Incidence of Erectile dysfunction	0	0.0	1	2.6	19	48.7	19	48.7	0	0.0	39	100.0

Table XIII. ASSOCIATION OF VARIABLES OF PRE INTERVENTION SHIM SCORE WITH DEMOGRAPHIC VARIABLES

Demographic Variables	No ED (22-25)	Mild ED (17 –21)	Mild to Moderate ED (12 – 16)	Moderate ED (8 – 11)	Severe ED (22-25)	Total	Chisquare test	P-Value	Sig. at 5% level
Age Group (yrs)									
26 – 35	0	1	4	4	0	9	3.991	0.407	Not
36 – 45	0	0	10	8	0	18			
46 – 55	0	0	5	7	0	12			
Total	0	1	19	19	0	39			
Marital Status									
Unmarried	0	0	1	1	0	2	0.055	0.973	Not
Married	0	1	18	18	0	37			
Total	0	1	19	19	0	39			
No. of Children									
0	0	1	1	2	0	4	8.815	0.184	Not
1	0	0	7	6	0	13			
2	0	0	9	9	0	18			
3	0	0	1	1	0	2			
Total	0	1	18	18	0	37			
Types of Surgery									
Anterior Resection	0	1	13	17	0	31	2.847	0.241	Not
Abdomino-Perineal Resection	0	0	6	2	0	8			
Total	0	1	19	19	0	39			
Radiation therapy details-Dose									
NACTRT	0	1	16	17	0	34	0.386	0.824	Not
Nil	0	0	3	2	0	5			
Total	0	1	19	19	0	39			
Radiation therapy									
<50GY/ 25#	0	0	4	3	0	7	0.540	0.764	Not
≥50GY/ 25#	0	1	12	14	0	27			

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