

Does early return to physical activity affect the cure rates for mid-urethral sling surgery?

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Abstract

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Aim: The aim of this study is to assess the effect of early physical activity on objective and subjective cure rates after a mid-urethral sling.

Methods: This is a pilot study in which 50 patients with primary urodynamic stress incontinence underwent sling surgery and were assigned to either the Early Physical Activity (EPA) or NO Physical Activity (NPA) groups. All patients were evaluated at 3 months with urodynamic studies and questionnaire.

Keywords: cure rates, mid-urethral sling, early physical activity, post-operative.

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Results: The objective cure rate in the early activity and no activity group were 76% and 88% respectively ($p=0.465$). Meanwhile, the subjective cure rate in the activity group was 56% compared to 68% in the control group ($p=0.56$).

Conclusion: There was no statistically significant difference in subjective or objective cure rates between the two groups at three months.

Introduction

There has been a long standing notion that restriction of activity during the period of convalescence following pelvic reconstructive surgery plays a major role in determining the effectiveness of a surgery especially for the first six weeks. This restriction has minimal scientific evidence to support it [1,2].

In this pilot study we used the MiniArc™ sling for the treatment of stress urinary incontinence. Accordingly, we found no evidence-based guidelines through a Medline search from 1980–2010 using the following search criteria ‘early return to daily activity post incontinence surgery’, ‘activity restrictions after incontinence surgery’, ‘convalescence recommendations following incontinence surgery’, ‘physical activity and incontinence surgery’, ‘sexual function post incontinence surgery’ and ‘does a period of convalescence influence outcome of incontinence surgery?’ The aim of this study was to assess the effect of early physical activity on cure rates of mid-urethral slings.

Materials and Methods

In this study all patients were recruited from the urogynaecology clinic following the diagnosis of urodynamic stress urinary incontinence (USI). Ethics approval was received from our institution (HREC/09/QTHS/20). These patients were assigned to receive the MiniArc™ sling for the treatment of their USI. Patients with no concomitant reconstructive surgical requirements were randomly assigned to either prescribed early physical activity or no physical activity. Patients with other concomitant procedure requirements were assigned to the ‘no physical activity’ group only. This was to ensure that this study did not compromise the outcome of concomitant procedures performed [Table 2].

All patients received pre and postoperative counselling with regard to the objectives of the study, particularly the activities that the patients assigned to the activity group would be required to perform. The surgery was performed in a standard fashion per protocol established by the manufacturer [3]. All patients received post-operative written instructions and questionnaires which included the prescribed Activity leaflet, daily activity diary for the EPA group along with MBLUFTS and PGI-I which were administered for all patients [4]. The NPA group was given “standard” advice to avoid heavy lifting or strenuous activity for 4–5 weeks. In the absence of complications all patients were to be discharged on the day of surgery after a successful trial of void. In order to standardize “pelvic effort” it was imperative that the patients assigned to the Physical activity group did daily prescribed physical exercises over and above daily activity (see appendix). Patients were advised to keep a diary of all the activities including coitus, laundry, driving and sports. At 12 weeks all patients were followed up with urodynamic evaluation.

25 patients were recruited in each arm. Exclusion criteria from the study included previous anti-incontinence surgery, intrinsic sphincter deficiency, detrusor over activity, significant voiding dysfunction, lower urinary tract anomaly, neurogenic bladder disorders, previous radiation therapy to pelvis, past history of any fistula involving the urinary tract, allergy to polypropylene or local anaesthetic and any condition that could potentially prevent patient from undertaking prescribed exercises.

All patients had a detailed urogynaecologic history, physical examination and a multi-channel urodynamic evaluation. MBFLUTS and PGI-I questionnaires were employed both pre- and post-operatively to evaluate the impact of incontinence and voiding dysfunction on quality of life. Evaluation also included collection of intra-operative and post-operative complications.

Objective cure was defined as no leakage of urine on coughing during the stress test on Urodynamics. Subjective cure was defined as no urine loss reported by the patient during physical effort. Urodynamic techniques and measurements, terms and diagnostic criteria conform to the recommendations of the International Continence Society [5,6].

The Statistical Package for Social Sciences (SPSS 14.0) was used for data analysis. Continuous data were reported as the Mean \pm Standard Deviation (SD) and analysed with Student's t test. Categorical relationship were analysed by the χ^2 test with Yates' correction or Fisher's exact test, as appropriate. Probability values of <0.05 were considered statistically significant.

Results

From June 2009 to October 2009, 50 patients with urodynamic SUI were enrolled in the study. At 3 months all 50 patients were available for follow up. The population's demographic and clinical characteristics are shown in Table 1. Preoperative demographics, clinical characteristics and urodynamic parameters were similar in both groups except that there were a higher number of post menopausal women in the EPA group.

In the EPA group, 22 patients had MiniArc™ Sling surgery alone with three minor procedures performed concomitantly. In the NPA group, 7 (28%) patients had sling as the only surgery while 18 (82%) patients underwent various concomitant reconstructive pelvic floor surgeries. Table 2 summarises the types of surgeries performed in both the EPA and NPA groups. All the cases were performed under a general anaesthetic. Of the total of 50 patients, 48 (92%) patients were discharged on the same day.

Table 1 Demographics.

| | EPA | NPA | P value |
|---|-------------------------|-------------------------|----------------|
| Age (years) | 47 (41 – 59) | 54 (43 – 64) | 0.299 |
| Parity, median (range) | 3 (2 -3) | 3 (2 – 4) | 0.455 |
| BMI (kg/h²) | 25.5 (23.6 – 29.4) | 25.8 (22.3 – 37.7) | 0.793 |
| Abdominal Hysterectomy, n (%) | 1 (4) | 1 (4) | 1 |
| Vaginal Hysterectomy, n (%) | 2 (8) | 2 (8) | 1 |
| Menopause, n (%) | 8 (32) | 15 (60) | 0.047 |
| Cystometry capacity (ml, mean \pm SD) | 439.8 (SI \pm 75.8) | 441.3 (SI \pm 44.3) | 0.933 |
| Uroflow (ml/s, mean \pm SD) | 33.6 (SI \pm 14.6) | 29.0 (SI \pm 8.4) | 0.17 |
| MUCP (cm H₂O, mean \pm SD) | 43.7 (SI \pm 17.6) | 40.6 (SI \pm 17.6) | 0.54 |

Table 2

| Types of Surgery | EPA, n (%) | NPA, n (%) |
|--|-------------------|---------------------|
| MiniArc alone | 7 (28) | 22 (88) |
| Other concomitant procedures | | |
| Posterior Fascial Repair | 3 (12) | 0 (0) |
| Posterior Fascial Repair & Anterior Fascial Repair | 3 (12) | 0 (0) |
| Posterior Fascial Repair & Anterior Fascial Repair & Perineoplasty | 2 (8) | 0 (0) |
| Posterior Fascial Repair & Perineoplasty | 2 (8) | 0 (0) |
| Perineoplasty | 2 (8) | 0 (0) |
| Posterior Mesh Repair (APOGEE) | 1 (4) | 0 (0) |
| Posterior Mesh Repair (POSTERIOR ELEVATE) | 1 (4) | 0 (0) |
| Fentons | 2 (8) | 0 (0) |
| Laparotomy & Right Salpingoophrectomy | 1 (4) | 0 (0) |
| Partial Colpocleisis | 1 (4) | 0 (0) |
| Microwave Endometrial Ablation (MEA) | 0 (0) | 2 (8) |
| Intravesical Steroid Injection | 0 (0) | 1 (4) |
| TOTAL | 25 (100) | 25 (100) |

Table 3 depicts the duration taken by patients in the EPA Group to return to their routine activities like cooking, washing, laundry and driving. 36% of the women were able to return to their daily lifestyles the following day. 96% patients were able to resume their routine within the first week of surgery. All patients were compliant in performing the prescribed daily exercises as well.

Table 3

| Return to routine daily activities (days from operation) | Number of patients | Percentage (%) |
|---|--------------------|----------------|
| Day 2 | 9 | 36 |
| Day 3 | 3 | 12 |
| Day 4 | 3 | 12 |
| Day 5 | 2 | 8 |
| Day 6 | 2 | 8 |
| Day 7 | 5 | 20 |
| After 1 week | 1 | 4 |
| Total | 25 | 100 |

Only 15 patients (60%) in the EPA Group were sexually active. Of the sexually active women, 4 (26.7%) patients resumed sexual activity within 2 weeks while 10(66.7%) took between two and four weeks respectively. After the sixth post-operative week, all 15 patients reported resumption of sexual activity. None of these patients reported any problem during their sexual activity except one patient who complained of discomfort owing to mesh exposure. Table 4 summarises the sexual function in the Activity Group. Of the 14 patients in the EPA group who had sexual intercourse within 6 weeks of surgery, only 2 patients complained of leakage of urine on urodynamics.

Table 5 shows the objective cure rate for USI in the NPA group was 88% after 3 months compared to 76% in the EPA group ($p=0.46$), while the subjective cure rate for USI was 68% and 56% respectively ($p=0.56$) which were statistically not significant. Two patients (8%) in each arm had voiding dysfunction of which two were treated conservatively and the other two were treated surgically with sling division.

De novo urge incontinence was found in 16% of patients in the NPA group compared to 4% in the EPA group. However, Urodynamic Detrusor overactivity was demonstrated only in one patient in the NPA group and two patients in the EPA group. Overactive Bladder symptoms were the main complaint among the 24% of patients in the NPA group compared to 16% of patients in the EPA group. 6 of these patients with distressing OAB symptoms were given trial of anti-muscarinic drugs. De novo urge incontinence and OAB symptoms were higher in the NPA groups with none of the complications reaching statistical significance .

All the patients in the NPA group were satisfied with the outcome of the surgery whilst two patients (8%) in the EPA group were partially satisfied due to worsening of their overactive bladder symptoms. 68% of the patients in the EPA group were very satisfied with the outcome of the surgery compared to 64% in the NPA group.

Table 4

| | Number of patients | Percentage (%) |
|--|--------------------|----------------|
| Sexual function before the operation | | |
| Sexually active | 15 | 60 |
| Sexually not active | 10 | 40 |
| Duration taken to resume sexual function (week) | | |
| Week 1 | 1 | 6.7 |
| Week 2 | 3 | 20.0 |
| Week 3 | 4 | 26.7 |
| Week 4 | 3 | 20.0 |
| Week 5 | 1 | 26.7 |
| Week 6 | 2 | 13.3 |
| Beyond 6 weeks | 1 | 6.7 |
| Women who engaged in intercourse within 6 weeks of surgery | | |
| Continent at 3 months post surgery | 12 | 86 |
| Leaking at 3 months post surgery | 2 | 14 |

Discussion

The EPA group was able to achieve normal routine activity in addition to prescribed activity successfully without compromising their surgery. In fact, 24 out of 25 patients in the activity group were able to return to their daily activities within the first week of surgery quite effortlessly.

Through this pilot study we have tried to contest unsubstantiated traditional beliefs that early return to physical activity after incontinence surgery, a short period of convalescence and an absence of restrictions during convalescence are important factors for failure of surgery. The rationale of these older recommendations revolves around the theory that keeping the abdominal and vaginal pressure low in the convalescence period probably helps prevent wound dehiscence, promotes tissue repair and perhaps in the long run prevents recurrence. However, there is very little evidence to recommend the type or duration of restriction of physical activity [1,2].

In recent times there have been a few studies that have attempted to challenge the recommendations on convalescence period and activity restrictions for a variety of surgical procedures. Fast-track vaginal surgery programs with short hospitalisation lasting 24 to 48 hours did not result in increased incidence of pain, bleeding or rupture of the vaginal scar and therefore it did not appreciably increase the risk of recurrence pelvic organ prolapse [8]. A short period of convalescence of 1 to 3 weeks with restrictions on lifting more than 10 kg, sports and sexual intercourse did not result in an increased recurrence of pelvic organ prolapse (POP) compared to 6 weeks convalescence [9]. A study from Denmark reveals that by simply changing the recommendations for the convalescence period after inguinal hernia surgery, the need for sick leave was reduced from a median of 3 weeks to 6 days [10]. Another study has shown that the risk of recurrence after hernia surgery is not increased by less restrictive

Table 5

| Results and complications at 3 months post operation | EPA , n (%) | NPA , n (%) | p value |
|--|---------------|---------------|---------|
| Cure rates | | | |
| Negative stress test | 22 (88) | 19 (76) | 0.46 |
| Women without SUI symptoms | 17 (68) | 14 (56) | 0.56 |
| Satisfaction scores (0-10) | | | |
| Very satisfied (9-10) | 16 (64) | 17 (68) | 0.76 |
| Satisfied (6-8) | 9 (36) | 6 (24) | 0.35 |
| Partially Satisfied (3-5) | 0 (0) | 2 (8) | 0.15 |
| Not Satisfied (0-2) | 0 (0) | 0 (0) | - |
| Complications | | | |
| Voiding dysfunction | 2 (8) | 2 (8) | 1.0 |
| Urodynamic Detrusor Overactivity | 1 (4) | 2 (8) | 0.55 |
| Denovo Urge Urinary Incontinence | 4 (16) | 1 (4) | 0.16 |
| Overactive Bladder symptoms | 6 (24) | 4 (16) | 0.48 |
| Urinary Tract Infection | 1 (4) | 0 (0) | 0.31 |
| Groin pain | 1 (4) | 0 (0) | 0.31 |
| Mesh Exposure | 1 (4) | 1 (4) | 1.0 |
| Dysparuenia | 1 (4) | 0 (0) | 0.31 |
| Orgasm pain | 1 (4) | 0 (0) | 0.31 |

Table 6

| MINISLING | Objective outcome | Subjective outcome |
|----------------------------|-------------------|--------------------|
| MAS | 82 | 62 |
| Jiménez Calvo J et al | | |
| MiniArc™ | 90.2 | 80 |
| TVT Secur™ | 80.4 | 80 |
| Jiménez Calvo J et al | | |
| MiniArc™ | 92 | 90 |
| Sottner O et al | | |
| MiniArc™ | 76.7 | 86.8 |
| De Ridder D et al | | |
| MiniArc™ | 85 | NA |
| Monarc™ | 89 | NA |
| Gauruder-Burmester A et al | | |
| MiniArc™ | 82 | 69.1 |
| 77.8 | | |
| Debodinance P et al | | |
| TVT Secur™ | 83 | NA |
| Khandwala S et al | | |
| TVT Secur™ | 79 | 85 |
| Gopalan P et al(our data) | 82 | 62 |

recommendations [11]. In a recent edition of a gynaecologic textbook suggested that activity can be gradually increased in the first two post-operative weeks. From the beginning of the third week the patient may go outdoors and, if able, drive at the end of the month [12]. Recent prospective studies have shown that the majority of patients had returned to normal levels of activities including cleaning, shopping, driving, outdoor activities, and non-strenuous work within 1 to 2 weeks post vaginal surgery [13,14].

Ottensen M et al [2] has shown that chronic coughing and chronic straining to pass stools when constipated seem more important as creators of high vaginal/abdominal pressure which could play a major role in the progression and recurrence of pelvic organ prolapse by causing more stress on a healing scar than controllable activities, e.g. lifting. In the study of Weir et al. [1], lifting moderate weights did not create higher abdominal pressure than unavoidable daily activities in a group of healthy volunteers. Unlike physical activities, a high intra-abdominal baseline pressure is correlated to a high BMI and to a high prevalence of urinary incontinence [15,16].

As most patients undergoing incontinence surgery are elderly, one may speculate that some of them may lose agility during a convalescence period with too many and, perhaps, unnecessary restrictions. Therefore, post-operative counselling should concentrate more on treating chronic cough and constipation than restrictions of moderate physical activities.

In conclusion, our study has attempted to show that women can be allowed to return to early physical activities without necessarily changing the outcome of the surgery. In this pilot study, the objective cure rates (88% versus 76%) and subjective cure rates (66% versus 56%) were higher in the NPA group as compared to the EPA group. Although these results were not statistically significant the lower cure rates among the EPA group could be attributed to the significantly higher number of post menopausal women in it. Studies have shown how menopausal effect on tissue quality could influence the efficacy of incontinence surgeries [17,18]. Moreover these results compare favourably with other studies done with Minislings [Table 6 & 19-25]. Restrictions advised during the convalescence period potentially have physical, social and economic ramifications. Limitations of our study include a small sample size since there was no other data to refer from. We admit to the need for more long-term prospective studies to study the tenuous and perhaps questionable link between surgical outcomes of surgery for urinary incontinence and early return to physical activity with different rehabilitation regimens. The results of this study should pave way to further studies using "standard slings" and perhaps single compartment prolapse surgery.

Appendix I

MANDATORY DAILY PELVIC EFFORT FOR EPA GROUP

| Activity | Repeats |
|---|---------|
| Knee bends | 10 |
| Sit-stand | 10 |
| Jumps | 10 |
| Pick up heavy shopping bag(4kg to 10kg) | 10 |

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