Prospective observational study of the impact of vaginal surgery (pelvic organ prolapse with or without urinary incontinence) on female sexual function

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Prospective Observational study of the impact of vaginal surgery (Pelvic Organ Prolapse +/- Urinary Incontinence) on female sexual function.

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All the authors have nothing to disclose.

Conflict of Interest

The authors declare that they have no conflict of interest.

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Abstract

Introduction and Hypothesis:

There is a difference of opinion in the literature as to whether or not pelvic organ prolapse (POP) is a direct cause of FSD. Sexual function in women is negatively impacted by presence of urinary symptoms. Sexual dysfunction(SD) might be improved, unchanged or worsened by pelvic floor surgery.

Methods:

In this study we observed the SD and impact of surgical intervention on female sexual function using validated questionnaire (PISQ-12) in women undergoing pelvic organ prolapse +/- urinary incontinence surgery. 200 women were recruited and followed up 6 and 12 months post operatively.

Results:

Sexual function as measured by the PISQ-12 improved after surgery irrespective of the nature of surgery or the patient's past gynaecology history. Improvement in sexual function was seen by 6 months (97 patients) post-surgery ($p < 0.05$) after which(assessed at 12 months – 80 patients) no further change in PISQ-12 was observed. Improved sexual function was associated with better patient satisfaction post-operatively.

Conclusions:

Sexual function improved after surgery irrespective of nature of surgery and patient past gynaecology history. Our study will help in counselling women with POP and/or UI undergoing surgery about potential improvement in sexual function.

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Keywords: Female sexual function, validated questionnaire, vaginal surgery

Summary: Majority of women will have improvement in sexual function after prolapse +/- incontinence surgery and this is strongly positively associated with patient satisfaction.

INTRODUCTION

Female Sexual Dysfunction (FSD) is a common problem, with data from the National Health and Social Life Survey showing that 43% of women aged 18–59 years experiencing some form of FSD(1). The aetiology of FSD is multifactorial, with hormonal, psychological, anatomical, vascular and neurogenic elements all being possible aetiological factors(2).

Pelvic Organ Prolapse (POP) and urinary incontinence (UI) form a major health burden to women affecting 41-65% of women. Large population study suggests that the prevalence of stage three or four prolapse is in the range of 2-11% (3,4). An epidemiological study reported UI to affect up to 41% of the women. (5). At least 1 in 3 parous women undergo at least one surgery for these conditions by the age of 80 years (6). Women with POP and /or UI are at higher risk of sexual dysfunction (7, 8, 9,10,11) compared to those without.

Traditionally pelvic floor surgeons have assessed the outcome of vaginal repair surgery by the degree of restoration of normal pelvic anatomy. Increasingly, however the effect of prolapse surgery upon a woman's sexual function is being used as an outcome measure of the success of surgical repair (12,13), especially since the introduction of vaginal mesh repairs for prolapse (14).

There is a difference of opinion in the literature however as to whether or not Pelvic Organ Prolapse (POP) is a direct cause of FSD. It may not be the prolapse itself but rather the associated coital incontinence that predicts sexual dysfunction. Likewise, it appears that vaginal anatomy per se is not an independent factor in the aetiology of

FSD: neither vaginal calibre, nor length, nor atrophy, nor menopausal status have a direct influence on the presence of FSD(22).

AIMS

In this study we aimed to assess the incidence of FSD in a group of sexually active women with stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP) awaiting surgical management. The secondary aim was to determine whether vaginal surgery for prolapse or UI leads to alteration in sexual function and to compare SF in subjects undergoing POP or UI surgery alone with POP surgery combined with UI surgery.

STUDY POPULATION

The study was co-ordinated from the Department of Urogynaecology at the South Glasgow University Hospital in their established Urogynaecology and Pelvic Floor Dysfunction Research Unit. All women undergoing any type of POP repair and/ or urinary incontinence surgery were invited to participate in the study. 200 women were recruited through the Urogynaecology clinics across the service over a 12-month period from June 2011 to May 2012. All women gave written informed consent to be involved in the study.

FUNDING

Project was funded by the Department of Urogynaecology, South Glasgow University Hospital.

INCLUSION CRITERIA

1. Women on the waiting list for surgical repair of POP, UI procedure or both, and;
2. Who have been sexually active in the last 6 months and expect to remain so post-operatively, or;

EXCLUSION CRITERIA

1. Women under 18 years of age
2. Women unable to understand information leaflet
3. Women unable to complete the questionnaire

DATA COLLECTION

Patient's demographics and details about their surgical procedure(s) were obtained from the patient's hospital records.

METHODOLOGY

This was a prospective observational study. Ethical approval was obtained from West of Scotland Ethics Committee. Reference number: 10/S0709/69; 16/03/2011.

Women complaining of symptomatic pelvic organ prolapse and/or SUI who were on the waiting list for pelvic prolapse surgery (POP) +/- urinary incontinence (UI) surgery were recruited at preoperative assessment visit or during hospital admission for their procedure. Consenting participants completed the preoperative questionnaire which included primary and secondary outcome measures prior to surgery.

At 6 and 12 months after surgery a further set of questionnaire(baseline questionnaire and a self designed questionnaire appendix 1) was sent to women by

post, along with a stamped addressed envelope, to be completed at home and returned. Women who did not respond within 2 weeks were sent a reminder letter and questionnaire, and then they were contacted by telephone if there was no response after a further 2 weeks.

Primary outcome

Primary Outcome was to assess incidence of sexual dysfunction by condition specific validated quality of life assessment tool Prolapse/urinary incontinence sexual questionnaire short form (PISQ 12) score. (Rogers 2001, 2003)

Secondary outcomes

Secondary outcome was the change in PISQ-12 and International consultation on Incontinence Questionnaire – Vaginal Symptoms (ICIQ-VS) between baseline and 6 and 12 months after surgery. We also assessed urinary incontinence symptom distress and its life impact at 6 and 12 months using urogenital distress inventory short form (UDI-6) and Incontinence Impact Questionnaire IIQ-7. Patient satisfaction with surgery was measured using a study specific , non validated instrument (appendix 1) at 6 and 12 months.

Analysis

We tabulated descriptive statistics, reporting baseline demographics and clinical characteristics with means and SDs, or medians and IQRs as appropriate. A paired t-test was used to compare baseline, 6 month and 12 month scores, and analysis of variance to test for differences between surgery groups and post operative satisfaction levels. Data were analysed in SPSS version 19 and a 5% level of significance was used throughout.

Results

Two hundred women were recruited of which 180 (90%) returned completed baseline questionnaires. At 6-months 97 (48.5%) patients returned completed questionnaires. 87 (43.5%) questionnaires were returned completed at 12-months (Figure 1).

The mean age of participants was 54.4 years (SD 10.1). All women except 3 were parous with a median parity of 2 (range 0-5). 121 (67.2%) women were post-menopausal out of which 15 (8.3%) were on HRT at the time of their surgery. A significantly higher proportion of women who had surgery for prolapse were menopausal (Chi-square = 9.412, df = 2, P = 0.009). The majority of women who had surgery for POP (98%) had stage II or greater prolapse (Table 1).

Thirty-seven (19.5%) women had POP surgery in the past, of which the majority had conventional prolapse surgery without the use of mesh. Four (2.2 %) patients had surgery using mesh graft and 2 (1.1%) had both conventional and surgery using mesh. Seventeen (9.5%) patients had a previous UI procedure. One hundred and sixteen (68%) patients had no documented urinary symptoms (table 1).

A total of 130 women underwent POP surgery, 29 had UI surgery and 21 women had both POP and UI surgery (Table 2).

Sexual function

Overall the mean baseline PISQ-12 score in our study population was 30.54 (SD 6.55). There was no statistical difference in baseline PISQ-12 in women as per their age, parity, menopausal status or whether they had previous POP and /or UI surgery(table 3). There was also no statistically significant difference in the baseline

PISQ-12 between groups of women awaiting only POP surgery or only UI surgery or both POP and UI surgery (Table 4).

For all women the mean PISQ-12 score increased (improved) to 33.4 (SD 7.36) at 6 months and 33.5 (SD 7.40) at 12 months (Table 3). The improvement in PISQ-12 score from baseline to 6 and 12 months was statistically significant (Table 3) but not from 6 months to 12 months. The improvement in PISQ-12 was not significantly different between the groups of women having POP surgery, UI surgery or both POP and UI surgery (ANOVA F=2.266, df=2, p=0.109). It was also not influenced by any of the above mentioned demographic characteristics.

Improvements in UDI-6, VS and IIQ-7 scores from baseline to 6 months were statistically significant but not from 6 to 12 months, similar to PISQ-12 scores (Table 4).

No significant difference was seen between surgery types (no mesh, vaginal mesh for prolapse, mesh for UI, abdominal mesh for prolapse) in the change in PISQ-12 score from baseline to 6 months (ANOVA F = 1.463, df=3, p=0.230), specifically there was no difference between women having prolapse surgery with and without mesh (mean difference -0.99, standard error 1.49, p=0.510).

Other outcomes

Improvement in UDI-6 and IIQ-7 scores from baseline to 6 months was significantly different between the three surgery groups (ANOVA F = 15.9, df = 2, P<0.005 and F = 17.9, df = 2, p < 0.005 respectively). There was significantly more improvement in both UDI and IIQ scores for those women who had prolapse surgery alone compared to those women who had UI surgery only or those who had combined UI

and prolapse surgery. Improvement in VS scores from baseline to 6 months was not significantly different between groups (ANOVA F = 1.757, df = 2, p = 0.178).

Relationship with patient satisfaction

Seventy-seven (83%) women at 6 months and 60 (78%) women at 1 year reported being either satisfied or very satisfied with their surgical outcome. Being satisfied with surgery at 6 months (not satisfied / satisfied / very satisfied) was significantly associated with improvement in PISQ-12 score from baseline to 6-months (ANOVA F=5.915, df =2, p=0.004).

Improvements in UDI-6 (ANOVA F= 4.293, df =2, p=0.017) and VS scores (ANOVA F= 3.771, df = 2, p=0.025) at 6 months from baseline were also statistically significantly associated with patient satisfaction, however improvement in IIQ-7 was not (ANOVA F = 1.618, df = 2, p = 0.204).

Discussion

Surgery for prolapse has a role in reconstructing the local anatomy and alleviating some symptoms but does not necessarily ensure optimal sexual function. Sexual function might be improved (15, 16, 17), remains unchanged (8, 18) or worsened (19) after repair. Improvement in sexual function could also be due to emotional amelioration due to the cessation of incontinence (20, 21).

Most papers however only report on sexual function as a secondary finding. Most are retrospective in nature, and only a few have involved the use of a validated sexual function questionnaire (22). The prospective studies are either small with 3- 6 months follow up (8) or have used non condition specific questionnaires. Our study

has large numbers with 1-year follow-up and we have used a validated condition specific SF questionnaire with SF as the primary outcome.

Previously several retrospective and prospective studies have used either non validated SF questionnaires (8, 17) or self designed questionnaire or telephonic conversation. Recently condition specific validated sexual health questionnaires have been developed. At start of this trial the PISQ-31(Pelvic organ prolapse /Urinary incontinence Sexual Function Questionnaire) (including the short form PISQ-12) was the only validated condition specific (prolapse and UI) female sexual function questionnaire available. Other validated condition specific questionnaire that have been used to assess sexual function following pelvic floor surgery (e.g. Kings Health Questionnaire, ICIQ-VS) are quality of life questionnaires which include few questions addressing SF, they really deal with the overall impact of POP and/or UI surgery on the patients QoL. We therefore chose to use (the short form) PISQ-12 questionnaire for our study. However, we appreciate that this questionnaire only discriminates between women with and with out sexual dysfunction within the group of women with POP and UI and may not be optimal to detect SD following treatment as also concluded by Roos et al 2014 (23). We also understand that PISQ represents the positive effects of surgery well but does not reflect the possible negative effects of surgery on sexual function (16).

In our study population the mean PISQ-12 score was 30.54 (SD 6.55) with the maximum possible score of 48. Although a range of score for this instrument (PISQ 12) has not yet been established to classify severity of sexual dysfunction, we believe that our findings indicate that women enrolled in our study displayed a significant decrement in SF before POP and/or UI surgery. This observation is

consistent with several prior studies that found reduced SF in women with UI and/or POP or both (24,25,26).

The baseline PISQ-12 appears to be comparable to that reported by Brubaker in SISTEr Trial 2009 (mean 30.54) but lower than that reported by Glavind et al (mean 35.3) (27). This might be due to different baseline characteristics or different population.

We found statistically significant improvement in PISQ 12 score from baseline (30.54) to 6 months (33.45). Other studies which have reported statistical significant improvement in the score from baseline either have much smaller number of patients and shorter follow up.

In two different prospective study by Glavind et al (27) with short term follow up after prolapse surgery (n=81) reported baseline PISQ12 of 35.2 with postop improvement with positive difference of 3.0 (SD 3.8). Brubaker also reported significant improvement in PISQ-12 scores from 31.6 (SD 6.85) to 36.85 (SD 5.89). In a long term study by Lindquist et all where 63 patients after tension free vaginal tapes were followed for 4 years (n=44) used PISQ12 and quoted baseline mean PISQ12 of 33.8 which improved postoperatively(28).

Another prospective study by Thakar et al (16), in which 46 women were followed for 4 months post surgery showed significant improvement in SF after surgery for POP and UI at 4 months. Srikrishna et al (17) recruited 52 sexually active women and followed them up for 2 years using the GRISS and KHQ questionnaires, concluding that SF improved following surgery for POP with or out UI procedure. The results of the above two studies are not comparable as they used different questionnaires.

In a study by Paul et al (8) where 51 patients followed for 6 months, found that SF as measured by FSFI and sexual frequency were unchanged following vaginal surgery for pelvic organ prolapse with or without UI surgery, despite improvement in the stage of prolapse and incontinence symptoms. Weber et al 2005 reported that SF and satisfaction improved or did not change in most women after surgery for prolapse and /or UI. Rogers et al (15) reported mixed results with improved SF in 68 % of women and worsened function in 32% using 2 validated, condition specific questionnaire (PISQ-12 and IIQ-7) preoperatively and 3 and 6 months after surgery in 102 women with a mean age of 47 years. Similar to our study they observed no differences in the total SF scores between women who underwent POP and UI surgery and those who had only UI or only POP surgery.

We found statistically significant improvement in PISQ-12 score from baseline to 6 months with a positive score of 2.91. The minimum clinically important difference for the PISQ-12 is not yet determined. We observed positive improvement in SF scores by PISQ-12. Sloan et al proposed that a change of greater than half of the SD of the pre intervention score is a conservative estimate of an effect size that is clinically meaningful when using QOL questionnaires. (29).

We observed no further improvement in PISQ-12 score after 6 months. This suggests that any improvement in SF due to surgery is generally seen within the first 6-months; however the effect does appear to be maintained up to 1-year. Other studies using self designed non-validated questionnaire or much smaller numbers (15) have shown stability in SF outcomes over follow up period. We therefore suggest following this and our findings that assessment at 6 or 12 months are unlikely to be significantly different and the 6 month follow up can be used for comparison.

Success of surgery was defined as patient satisfaction. In our study improvement in PISQ-12 was observed in women with successful surgery and hence associated with patient satisfaction postoperatively. This was seen in all three subgroups. Improvement in SF was strongly influenced by the outcome of surgery i.e. patient satisfaction. Patient who were satisfied with their surgical outcome reported improvement in PISQ-12 score compared to those who were not either because of failure in improvement of symptom or new onset symptom like SUI following POP surgery. Patient who reported improvement in UDI 6 and VS scores also reported high satisfaction with their surgical outcome. It may be the presence or absence of Urinary symptoms rather than surgical technique which defines sexual function (26).

The numbers in each subgroup of surgery type were too small to make any comment on whether one technique/surgery improves SF more than the others. In our study we saw significant improvement in all groups of women with or without incontinent and hence can conclude that SF improves after surgery not only due to improvement in UI scores but also due to amelioration in symptoms due to POP.

In our study we found significant improvement in UDI and IIQ 7 in the POP only group where no UI surgery was performed and also significant improvement in VS score in the UI only group where no prolapse surgery was performed. This may have contributed to improvement in the PISQ-12 score post operatively in both the POP only and UI only groups (27). In a cohort of 1267 sexually active women Tok et al (30) found that women with prolapse had lower SF scores than those without the POP due to fear of UI during intercourse and also avoidance of sexual intercourse due to POP. It is therefore understandable that correcting the POP and improving

the body image and ameliorating the symptoms should lead to improvement in the SF.

We found improvement in PISQ-12 post operatively irrespective of technique or type of surgery performed for UI. Improvement in UI scores/symptoms was associated with patient satisfaction. Whilst our cohort size may have been too small to look for differences in surgical techniques, our findings are consistent with other authors. Brubaker 2009(26) (SISTEr trial) concluded SF improves after successful surgery for UI and was irrespective of type/technique of UI surgery and also stage of pop or with/out concomitant POP surgery.

Our study has lots of strength. It is a prospective study with a large number of patients. We have used a disease specific validated questionnaire PISQ-12. We have followed up our patients for 1 year postoperatively and have used multiple validated indices of bladder, POP and sexual function

We acknowledge the limitations to our study. There is no normative data for PISQ-12 established and questionnaire only demonstrates the effect of intervention (10). As this is only an observational study it is not possible to have a definite conclusion that it was the intervention that led to improvement. Degree of distress cannot be established as condition specific questionnaire measuring distress is not available at present (16). Sexual questionnaire IUGA Revised (PISQ-12 R) was not used as this was not available at the time when study was performed

The presence of POP and /or UI rather than severity of the problem or subtype of POP may impact SF. We did not do any objective follow up for prolapse so are unable to comment if improvement in sexual function as reported by patients is due to functional improvement rather than secondary to objective improvement in UI and

/or POP (31). Srikrishna et al (17) objectively assess women at follow up and found that the women with better supported pelvic floor were less likely to have sexual dysfunction.

We however instead used validated IIQ7 and VS questionnaires which evaluate the impact of POP and UI on social function. This may not exactly represent objective evidence of cure of UI and POP however, they do assess in a standardised and validated way the patient's overall improvement and perception of success of surgery. Thus IIQ7 and VS scores are relevant to study for sexual function after treatment of UI and or POP and are representative of successful treatment of POP and or UI surgery (15).

We also acknowledge that there were women who did not complete the forms at recruitment and follow up as they found it too embarrassing. However, our remaining cohort still gives us a larger sample than other reported studies.

Conclusion

Sexual function improves after surgery for POP and UI in the majority of patients. This improvement is strongly positively associated with patient satisfaction with the surgery. Improvement is seen by 6 months and tends to be maintained at 1-year.

Our study will help in counselling women with POP and/or UI undergoing surgery about potential improvement in SF.

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Appendix 1

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PATIENT SATISFACTION QUESTIONNAIRE

1. How satisfied are you with your surgery?

- Not satisfied
- Equivocal
- Satisfied
- Very satisfied

2. Have you had any postoperative complications since you have been discharged?

- Infection
- Bleeding requiring hospital attendance/admission
- Mesh erosion
- Others

3. How much do you think your symptoms have resolved?

1	2	3	4	5	6	7	8	9	10
Not resolved									completely resolved

4. Have you needed any further surgery for your symptoms?

- No
- Yes ……please specify……

5. What surgery and when did you get the repeat surgery?

…….
……..

Thanks for your time and help

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