HHS Public Access

Author manuscript

J Urol. Author manuscript; available in PMC 2018 December 01.

Published in final edited form as:

J Urol. 2017 December ; 198(6): 1397–1403. doi:10.1016/j.juro.2017.07.041.

Caution With Use Of The Expanded Prostate Cancer Index Composite-50 Urinary Bother Scale: How Voiding Dysfunction Modifies Its Performance

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Abstract

Purpose—We evaluated the agreement between patient-reported urinary function and bother, and sexual function and bother in radical prostatectomy (RP) patients to help inform possible non-functional, modifiable mechanisms for patient bother.

Methods—Patients were recruited from 2011-2014 at Washington University and Brigham & Women's Hospital. Urinary and sexual outcomes were assessed by the Expanded Prostate Cancer Index Composite-50 (EPIC-50) before, five weeks, and 12 months after RP. Spearman rank correlation coefficients and agreement/disagreement categories were used to describe the relation between function and bother.

Results—Despite moderate to good agreement between function and bother (urinary: r=0.51-0.69; sexual: r=0.65-0.80), discordant groups were observed. In the urinary domain, these groups were men disproportionately bothered by their function at baseline (16.9%) and 12 months post-RP (6.1%), and men less bothered by their function 5 weeks (26.8%) and 12 months post-RP (9.9%). Discordant groups in the sexual domain were men less bothered by their function at baseline (20.8%), 5 weeks (21.1%), and 12 months (15.7%) post-RP. Splitting the urinary bother scale into two sub-scales, one for incontinence-related bother to compliment the urinary function scale, which measures only incontinence, and one for voiding dysfunction-related bother, yielded

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Conflict of Interest: The authors declare no conflict of interest.

considerably better agreement (r=0.78-0.83 for urinary function and incontinence-related bother). Factors contributing to the group less bothered by their sexual function were unclear.

Conclusions—When using the EPIC-50, investigators should consider splitting the urinary bother scale by relation to incontinence to prevent distortion of function/bother and pre-/post-RP comparisons by co-existing voiding dysfunction.

Keywords

Prostate cancer; prostatectomy; urinary outcomes; sexual outcomes

Introduction

Prostate cancer (PCa) is the most commonly diagnosed cancer in developed countries and the second most frequently diagnosed cancer in men worldwide.[1] In developed countries, most men present with early-stage disease when a number of curative, therapeutic options exist (e.g., radical prostatectomy (RP) and brachytherapy) and survival rates are high. Therefore, an important factor upon which patients base their treatment decisions and an important determinant of their satisfaction with care are the side effects of therapy.[2, 3] As such, the importance of assessing patient-reported outcomes, such as treatment side effects and health-related quality of life (HRQOL), has gained recognition in the PCa field, and the science of improving PCa-related patient-reported measures (PROs) has advanced rapidly over the past 20 years.[4]

One such PCa-related PRO is the Expanded Prostate Cancer Index Composite (EPIC). This PRO, which is one of the most commonly used questionnaires in urologic research,[5] measures the side effects and associated HRQOL of PCa therapies.[3, 6-8] It was revised from the validated University of California, Los Angeles – Prostate Cancer Index to create a longer 50-item index (EPIC-50), as well as shorter 26- (EPIC-26) and 16- (EPIC for clinical practice (EPIC-CP)) item indices. The EPIC-50 index addresses four HRQOL domains, including urinary and sexual side effects, which are common following RP, as well as bowel and hormonal side effects, which are more common following radiation and androgen deprivation therapy, respectively.[9] Each domain includes sub-scales for both the functional side effects of therapy (“function”) and the annoyance created by these side effects (“bother”). Nevertheless, most research has focused on patient function, at least for RP, whereas considerably less research has focused on patient bother or satisfaction with their function.[4] Additionally, few studies have examined the degree of concordance, or perhaps more importantly, discordance between function and bother to identify possible non-functional mechanisms for bother (i.e., instances where bother does not match function), and thus possible modifiable targets to improve patient satisfaction following RP. Therefore, we used data from the Prostatectomy, Incontinence and Erectile function (PIE) study, a longitudinal study of PCa survivors, to examine the relation between function and bother in urinary and sexual outcomes.

Materials And Methods

Study population

Men scheduled to undergo RP for clinically diagnosed PCa were recruited into the PIE study from 2011-2014 at Washington University School of Medicine and Brigham & Women's Hospital. All scheduled men were eligible, except those who had previously undergone PCa therapy, radiation therapy to the pelvis (including bladder, rectum, or prostate), major pelvic surgery, or placement of a penile implant or artificial urinary sphincter. Men with known urethral stricture or colostomy, men who required chronic urinary catheterization, and men who did not speak English were also excluded.

Study design

Patient-reported urinary and sexual outcomes were assessed at baseline before RP, and 5 weeks and 12 months post-RP by the EPIC-50.[9] We used each of these time points in our analysis to explore the relation between function and bother across the full range of possible values (i.e., highest before RP, lowest 5 weeks post-RP, and intermediate 12 months post-RP). Although the EPIC-50 was developed and validated in PCa survivors on average 25.7 months (SD=13.0) after their primary therapy, it has been widely used to monitor PCa-specific PROs both pre-RP and post-RP beginning one month after surgery.[10-15]

For each EPIC subscale, a summary score was calculated and then transformed linearly to a 0-to-100 scale, with higher scores indicating better function and less bother. Agreement between function and bother was illustrated by scatterplots, and described by Spearman rank correlation coefficients. Levels of agreement (or disagreement) between function and bother were defined in relation to previously published minimally important differences (MIDs) in PCa survivors: 5-9 in the urinary domain and 10-12 in the sexual domain.[16, 17] Although these values were derived from the University of California, Los Angeles – Prostate Cancer Index and the EPIC-26 rather than the EPIC-50, the high correlation between the EPIC-26 and -50 (0.96-1.00)[18] suggests these MIDs likely also apply to the EPIC-50.[16] In our analysis, we used the upper bounds of the MID ranges, 9 in the urinary domain and 12 in the sexual domain, to provide conservative estimates of disagreement between function and bother. Scatterplots were color-coded to distinguish three levels of agreement (or disagreement): i) comparable function and bother; ii) minimally important difference between function and bother; and iii) large difference between function and bother (i.e., ≥2 times the MID).

The PIE study was approved by the institutional review boards at Washington University School of Medicine and Brigham & Women's Hospital. All participants provided informed consent.

Results

Of the 426 eligible participants who completed the baseline survey before RP, we excluded 22 who received additional therapies during follow-up and 55 who did not complete surveys at both 5 weeks and 12 months, leaving 349 (86.4% of 404) eligible participants. 313 of these men provided complete information on urinary outcomes at all three time points, and

294 provided complete information on sexual outcomes. The mean age of participants was 60.6 years (range: 42-78), and the majority were Caucasian (93.8%), had completed some college education or more (85.0%), earned ≥$75,000/year (62.8%), were married/living with a partner (87.2%), and had clinical stage T1 disease (76.7%) (Supplementary Table 1).

At baseline before RP, most men reported good urinary function (median=100) and not much urinary bother (median=89.3), and worse sexual function (median=62.8) and more sexual bother (median=75.0). Five weeks post-RP, all outcomes were considerably worse. In the urinary domain, the median value for function was 56.6, and that for bother was 67.9, and in the sexual domain, these values were 13.9 and 25.0, respectively. Twelve months post-RP, all values had improved greatly in the urinary domain (median for function=88.4; median for bother=87.5), and slightly in the sexual domain (median for function=28.4; median for bother=37.5).

Comparing function to bother, moderate to good agreement was observed for urinary and sexual outcomes at baseline (urinary: r=0.51; sexual: r=0.80), 5 weeks post-RP (urinary: r=0.69; sexual: r=0.65), and 12 months post-RP (urinary: r=0.58; sexual: r=0.77, all *p*-values<0.05, Table 1). In other words, men with better function tended to be less bothered compared to men with worse function, and vice versa. However, a few distinct groups with differing function and bother were observed at each time point. In the urinary domain, these groups were: i) men disproportionately bothered by their function at baseline (16.9%); and ii) men less bothered by their function 5 weeks post-RP (26.8%). Both of these groups persisted, but were considerably smaller 12 months post-RP (6.1% and 9.9%, respectively, Figures 1a-c). In the sexual domain, discordant groups of men less bothered by their **function** were observed at all three time points (baseline: 20.8%; 5 weeks post-RP: 21.1%; and 12 months post-RP: 15.7%, Figures 1d-f). These groups were also observed when we limited the analyses to men with good sexual function (EPIC score 60-100[19]) at baseline (5 weeks post-RP: 20.1%; and 12 months post-RP: 14.2%).

To gain some insight into these discordant groups, we reviewed all items in the urinary and sexual domains of the EPIC-50 questionnaire. In the urinary domain (Supplementary Table 2a, “original scales”), both the function and bother scores comprise items related to incontinence, but the bother scale includes additional items related to irritative/obstructive symptoms (items 6d-f). These types of symptoms are commonly observed in men with voiding dysfunction, including benign prostatic hyperplasia (BPH), overactive bladder (OAB), and chronic pelvic pain syndrome.[20-22] To separate the influence of incontinence from these conditions, we split the urinary bother items into two sub-scales, one for incontinence-related bother and the other for bother related to irritative/obstructive symptoms (Supplementary Table 2a, “modified scales”). This resulted in improved correlation between urinary function and bother related to incontinence at baseline and 12 months post-RP , and similar correlation 5 weeks post-RP. It also highlighted the difference between urinary function and bother related to irritative/obstructive symptoms (Table 1).

Considering the sexual domain (Supplementary Table 2b), the EPIC sexual function score comprises items related to both the ability to engage in sexual activity, as well as the frequency of activity, which we hypothesized might be influenced by the availability of a

sexual partner. Therefore, we repeated the analyses stratified by marital status as a surrogate marker of partner availability, but observed no differences in the estimates between married men and those living alone at any of the three time points (Table 1). Finally, no differences were observed in the percentages of discordant groups by post-RP pathology in either the urinary or sexual domain, providing no evidence for roles of either decisional regret (in the case of low-risk disease) or acceptance of the side effects of therapy in the case of high-risk disease (data not shown).

Discussion

Although moderate to good agreement was observed between urinary and sexual function and bother in our study of PCa survivors, a few distinct discordant groups were observed in both domains before and after RP. In the urinary domain, these groups were men disproportionately bothered by their function at baseline, men less bothered by their function 5 weeks post-RP, and small yet appreciable numbers of men in both groups 12 months post-RP. Discordant groups in the sexual domain were men less bothered by their function at all three time points. Further investigation of the urinary domain revealed that the bothered group was largely explained by differences in the components assessed by the urinary function and bother scales – i.e., the function scale assesses solely incontinence, whereas the bother scale assesses both incontinence and irritative/obstructive symptoms. Splitting the bother scale into two sub-scales (one for incontinence and one for irritative/obstructive symptoms) resulted in considerably better agreement between urinary function and incontinence-related bother alone. These findings suggest that irritative and obstructive symptoms associated with voiding dysfunction contributed to the discordance between function and bother. With respect to the sexual domain, it is unclear which factors contributed to lesser function-related bother, because our attempt at stratifying by marital status as a surrogate marker of partner availability and by pathologic stage did not explain this discordance.

The idea of splitting urinary incontinence from irritative/obstructive symptoms in the urinary domain of EPIC is not new. In the original EPIC-50 publication, the investigators created two additional scales based on factor analyses, one related to incontinence and the other to irritative/obstructive symptoms. However, as each of these scales consists of items that measure both function and bother, a direct comparison of function to bother is not possible.[9] The same is also true for the shorter version of EPIC, the EPIC-26, because its urinary incontinence scale includes items for both function and bother. Therefore, given the growing interest in PCa survivorship research on patient satisfaction, rather than solely on function,[23] we propose that future analyses use function and bother scales specific to incontinence and irritative/obstructive symptoms to facilitate a clearer comparison between function and bother.

In addition to function/bother comparisons, another place where problems may arise with use of the original urinary bother scale is in natural history studies that compare pre- to post-RP values.[24, 25] This comparison may be of concern because the urinary bother scale likely captures different conditions over time. Although we did not collect voiding dysfunction-specific measures during PIE, we believe that most urinary bother before surgery was likely

due to BPH, as the bothered group decreased considerably after RP, a therapeutic procedure for BPH. In contrast, five weeks after surgery when men's continence levels were at their worst, bother likely captured incontinence, as men's high degree of incontinence likely dominated their perception of bother. Finally, twelve months after surgery when men's continence had improved, bother likely reflected a combination of incontinence in men with residual incontinence, as well as persistent or newly-developed voiding dysfunction, such as OAB, chronic pelvic pain syndrome, and other lower urinary tract symptoms. For instance, in a recent study of RP patients, 19% of men developed de novo OAB, and 22% developed urinary symptoms, such as nocturia, over a median of 2.7 years of follow-up.[26]

Besides complicating comparisons of function to bother, differences in the conditions captured by the urinary bother scale may potentially lead to misleading trajectories of bother over time. For instance, if participants were more bothered by their BPH-associated irritative/obstructive symptoms pre-RP than they are by their incontinence-related symptoms post-RP, this could result in seeming improvements in urinary bother post-RP. This type of unexpected finding was recently observed in a retrospective cohort analysis by Murphy et al.[24] who observed significantly improved overall urinary outcomes post-RP (summarizing all EPIC-26 urinary items, including urinary incontinence, irritative/obstructive symptoms, and overall urinary bother) in men with severe urinary bother pre-RP, likely reflecting relief of their pre-RP BPH symptoms by prostatectomy. While these findings can readily be disentangled and interpreted with some thought, splitting the urinary bother scale into two sub-scales, one for incontinence and one for irritative/obstructive symptoms, would allow for a more straightforward interpretation.

To date, most of our discussion has focused on men disproportionately bothered by their urinary function pre-RP. However, an additional distinct group of men identified in our analyses were men less bothered by their urinary function 5 weeks and 12 months post-RP. This group was likely larger 5 weeks than 12 months post-RP because urinary function was considerably worse 5 weeks than 12 months after surgery. In the sexual domain, similar groups of men less bothered by their function were also observed at all three time points. Although speculative, we believe these discordant groups may be explained by better mental preparation for the side effects of therapy (e.g., realistic expectations for continence and potency following surgery), leading to a lower degree of bother despite large functional declines.[2728]In line with this hypothesis, Parker and colleagues[29] demonstrated improved short (1 week before surgery and morning of surgery) and longer-term (6 weeks, and 6 and 12 months post-surgery) mental and physical outcomes following a brief pre-surgical stress management intervention in their clinical trial of PCa survivors. Other possible mechanisms that might explain our findings include use of self-management strategies, support groups, or other forms of social support to help men cope with large functional declines post-RP.[28] We believe these types of interventions should be investigated further to allow men to maintain HRQOL through their immediate decline and subsequent recovery of function after surgery.[30]

Conclusions

In summary, our findings suggest that the EPIC-50 should be used with caution when assessing urinary bother because its performance may be distorted by co-existing or new-onset voiding dysfunction, such as BPH (pre-RP only), OAB, chronic pelvic pain syndrome, and other lower tract urinary symptoms. Therefore, we recommend separating the urinary bother scale into two sub-scales, one for incontinence-related bother and the other for irritative/obstructive symptom-related bother, to facilitate interpretation of function-bother comparisons (i.e., urinary continence function to urinary continence-related bother) and pre- versus post-RP comparisons. Future studies should also consider validating these modifications, extending function-bother investigations to bowel and hormonal domains for PCa patients treated with non-RP modalities, and exploring possible psychological mechanisms underlying our observed unbothered discordant groups for their potential to inform interventions aimed at improving post-treatment quality of life.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The PIE study was supported by the Transdisciplinary Research on Energetics and Cancer (TREC) Center at Washington University in St. Louis. The TREC Center was funded by the National Cancer Institute at NIH (U54 CA155496), Washington University, the Alvin J. Siteman Cancer Center, and the Foundation for Barnes-Jewish Hospital. We acknowledge all the participants in this study.

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Key of definitions for abbreviations

RP	radical prostatectomy
EPIC-50	Expanded Prostate Cancer Index Composite-50
HRQOL	health-related quality of life
PROs	patient-reported measures (PROs)
PIE	Prostatectomy, Incontinence and Erectile function
MIDs	minimally important differences
BPH	benign prostatic hyperplasia
OAB	overactive bladder

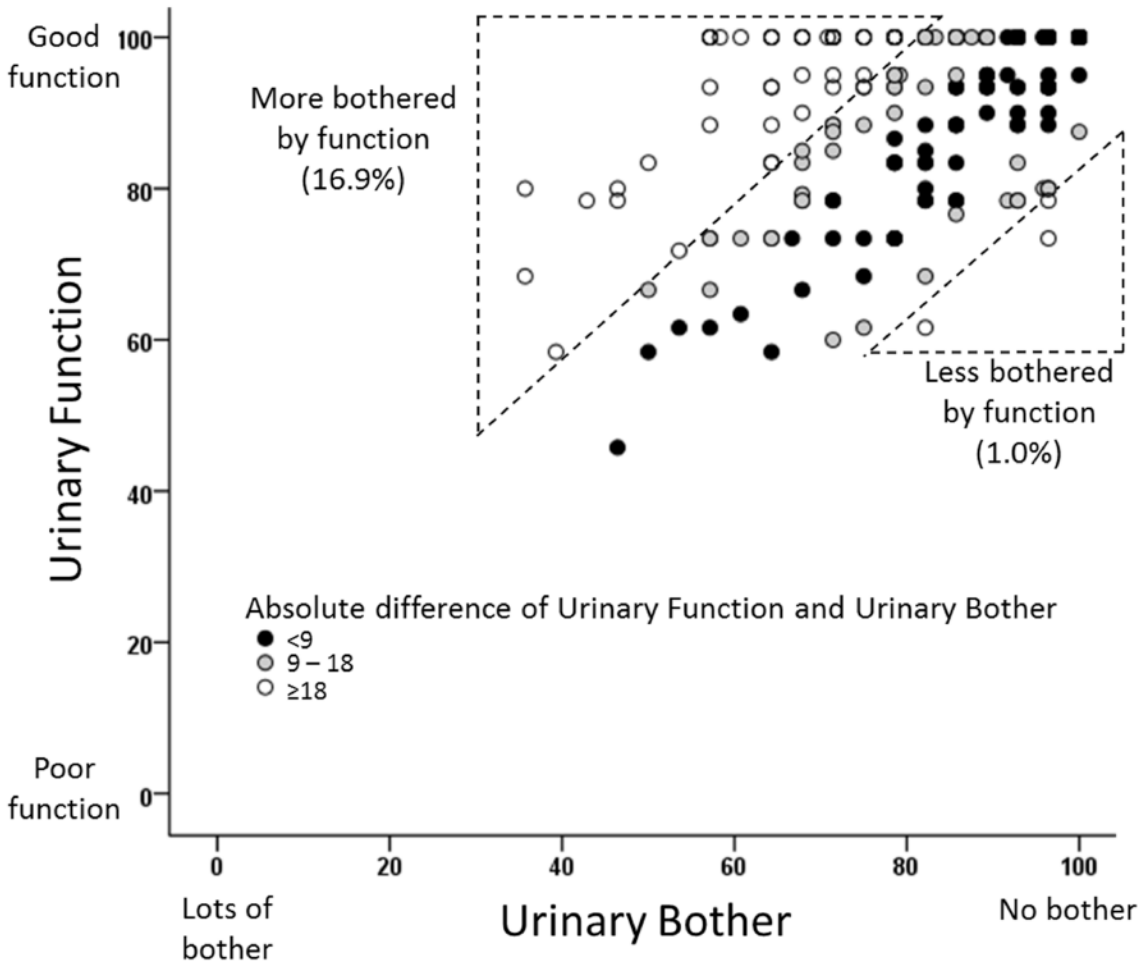

Figure 1a. Scatterplot of urinary function and bother scores in men in the Prostatectomy, Incontinence and Erectile function (PIE) study at baseline before radical prostatectomy, as measured by the Expanded Prostate Cancer Index Composite 50 (EPIC-50)

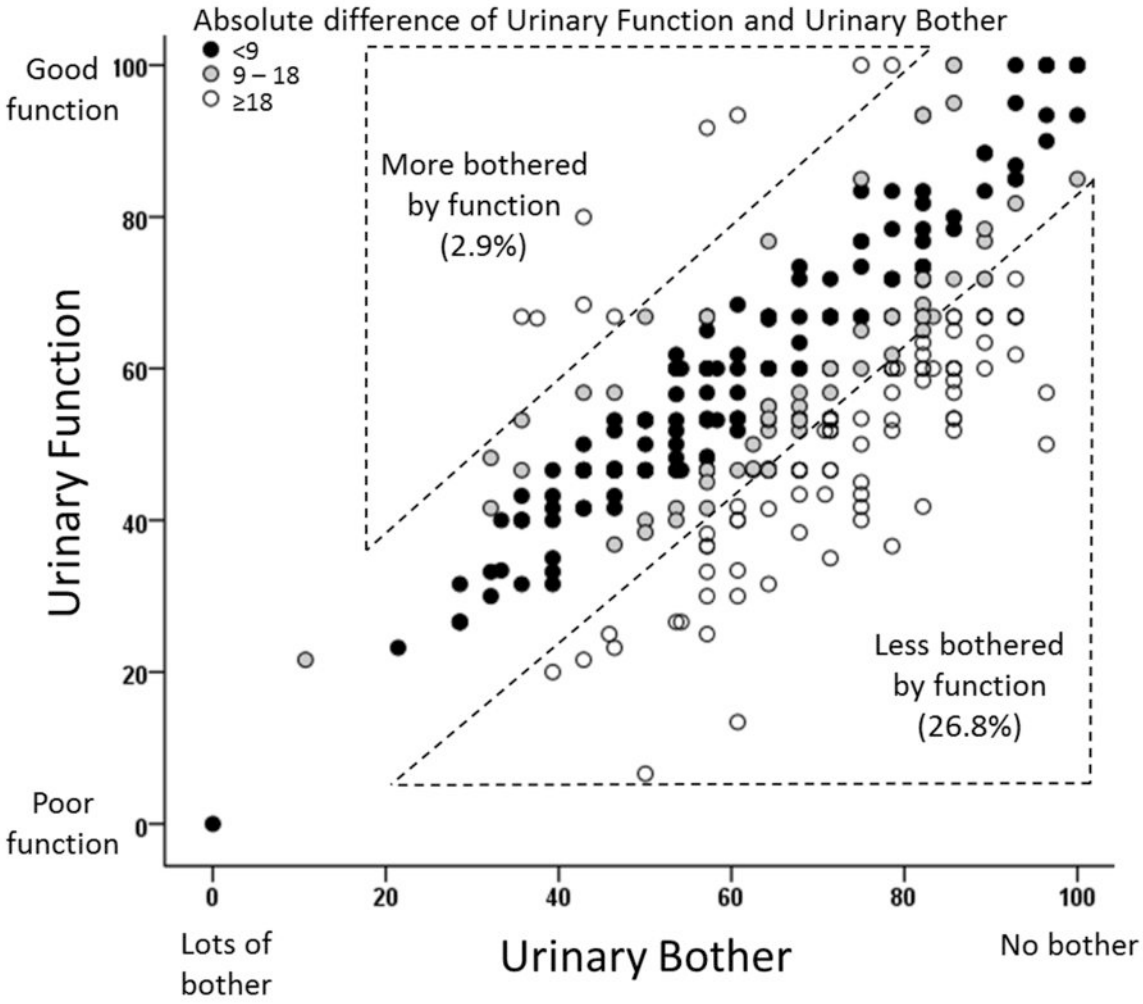

Figure 1b. Scatterplot of urinary function and bother scores in men in the Prostatectomy, Incontinence and Erectile function (PIE) study 5 weeks post-radical prostatectomy, as measured by the Expanded Prostate Cancer Index Composite 50 (EPIC-50)

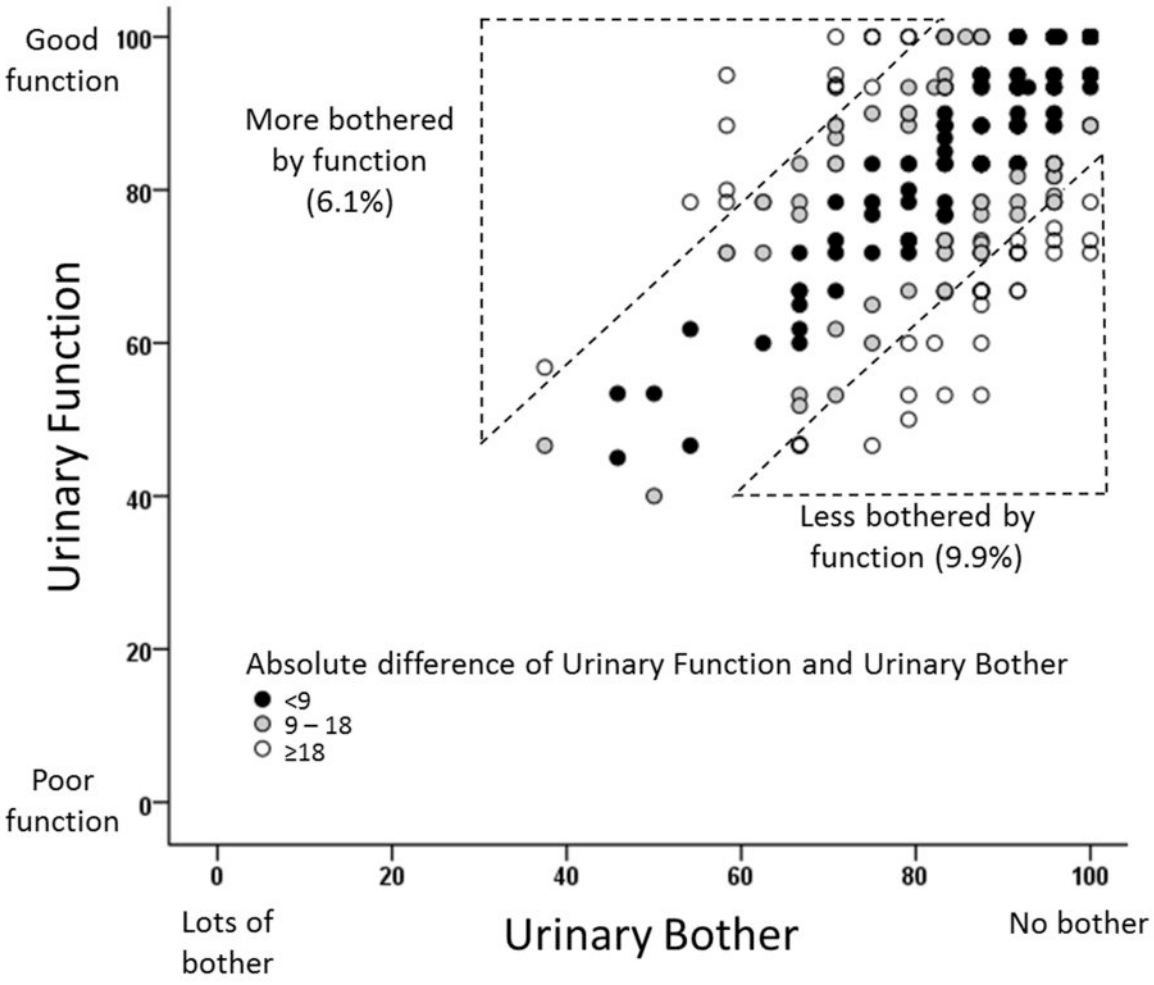

Figure 1c. Scatterplot of urinary function and bother scores in men in the Prostatectomy, Incontinence and Erectile function (PIE) study 12 months post-radical prostatectomy, as measured by the Expanded Prostate Cancer Index Composite 50 (EPIC-50)

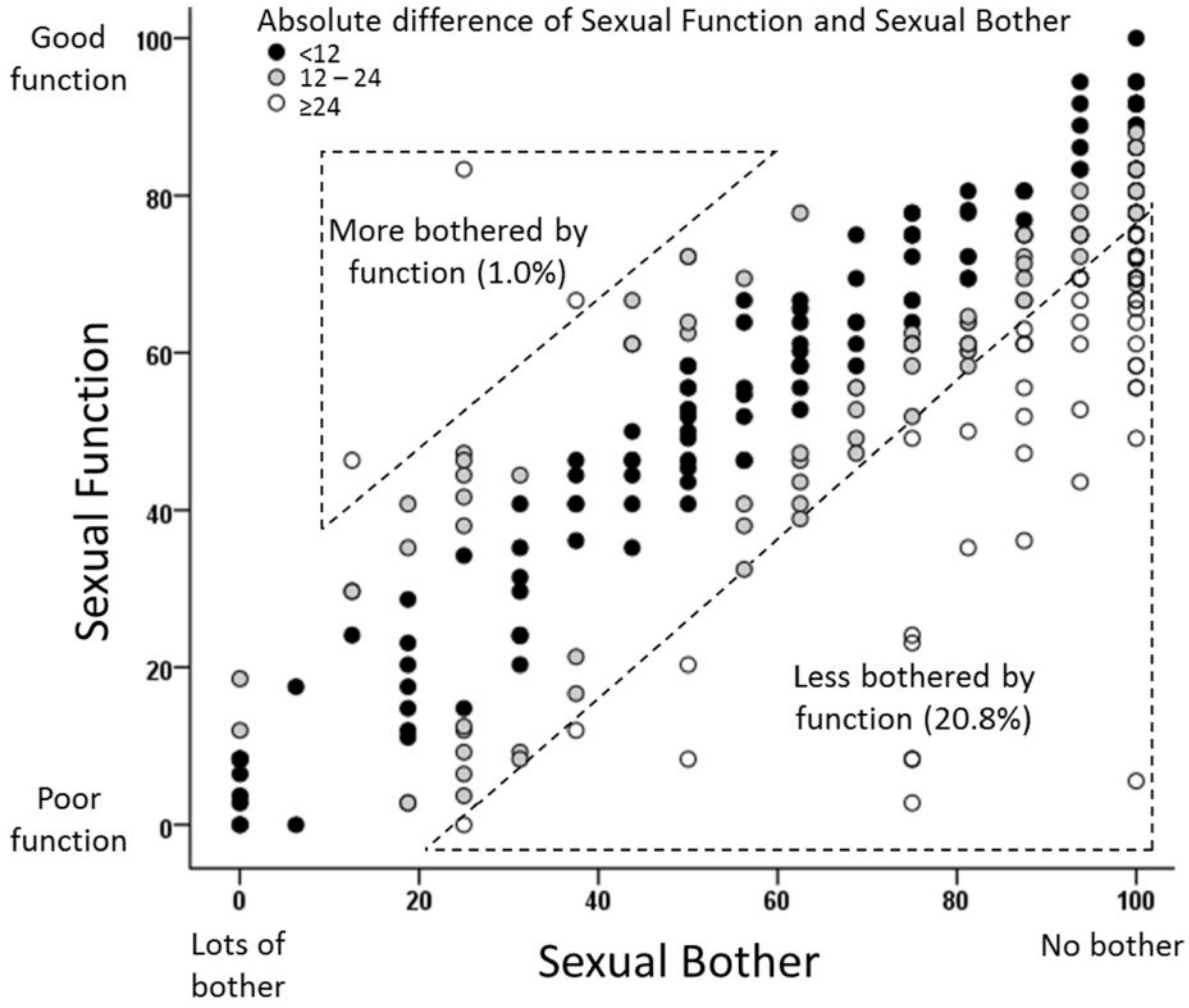

Figure 1d. Scatterplot of sexual function and bother scores in men in the Prostatectomy, Incontinence and Erectile function (PIE) study at baseline before radical prostatectomy, as measured by the Expanded Prostate Cancer Index Composite 50 (EPIC-50)

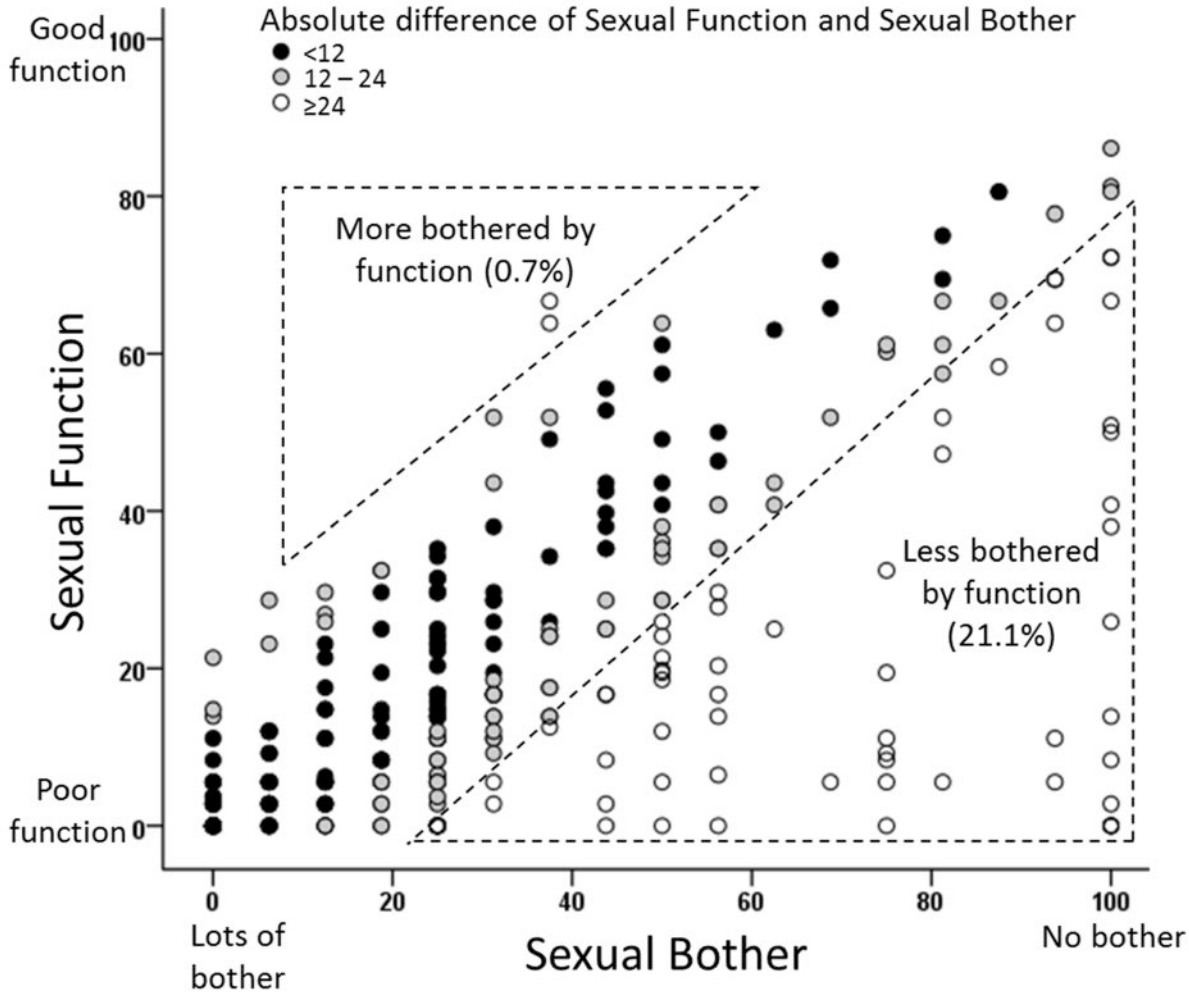

Figure 1e. Scatterplot of sexual function and bother scores in men in the Prostatectomy, Incontinence and Erectile function (PIE) study 5 weeks post-radical prostatectomy, as measured by the Expanded Prostate Cancer Index Composite 50 (EPIC-50)

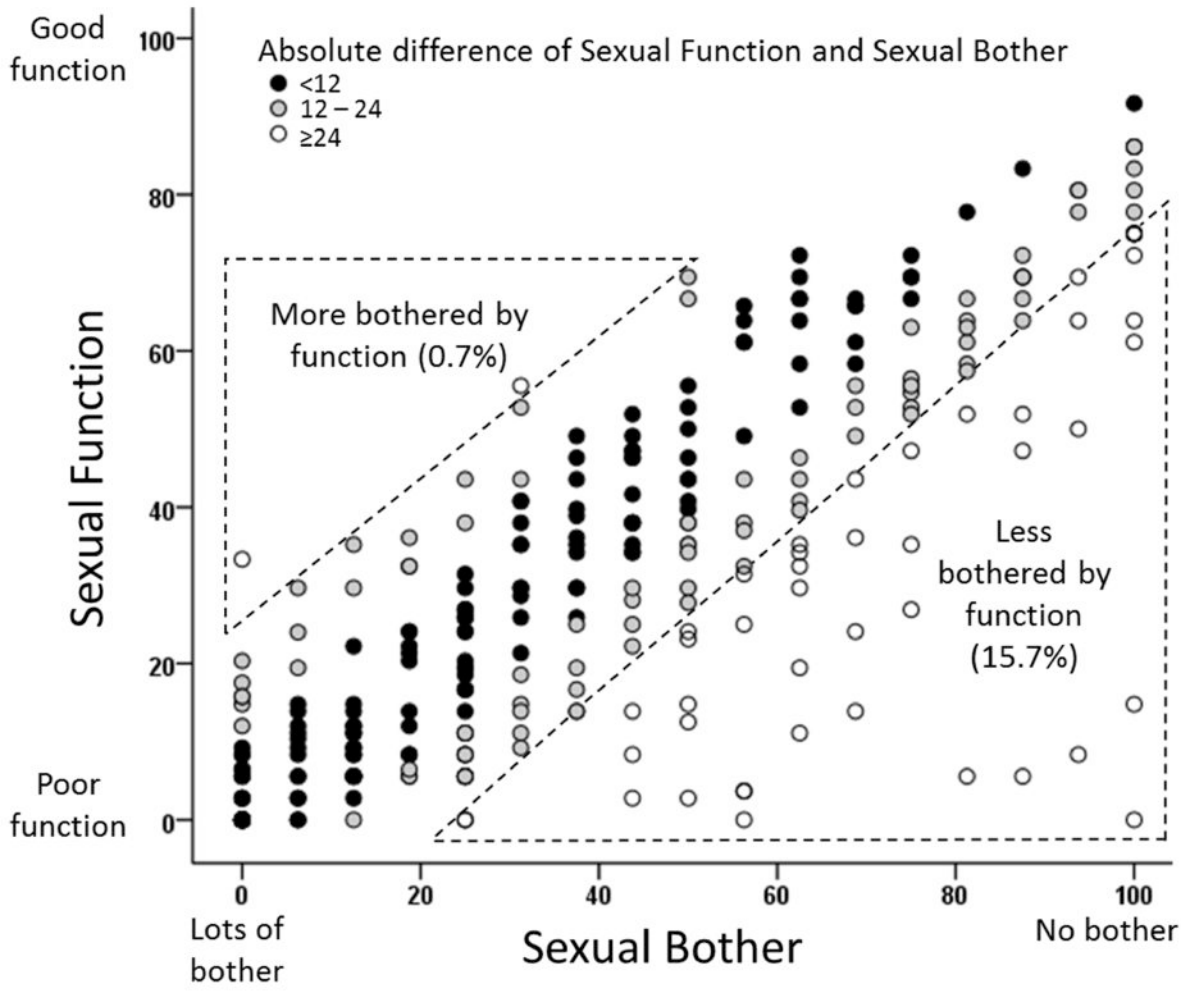

Figure 1f. Scatterplot of sexual function and bother scores in men in the Prostatectomy, Incontinence and Erectile function (PIE) study 12 months post-radical prostatectomy, as measured by the Expanded Prostate Cancer Index Composite 50 (EPIC-50)

Table 1

Agreement between patient-reported urinary and sexual function and bother in men in the Prostatectomy, Incontinence and Erectile function (PIE) study, as measured by the Expanded Prostate Cancer Index Composite 50 (EPIC-50)

	Pre-radical prostatectomy	Post-radical prostatectomy	
		5 weeks	12 months
Urinary outcomes:			
Original scales:			
r between function and bother[1]	0.51	0.69	0.58
% more bothered by function[2]	16.9	2.9	6.1
% less bothered by function[2]	1.0	26.8	9.9
Modified scales:			
r between function and incontinence-related bother[1]	0.79	0.78	0.83
r between function and irritative/ obstructive-related bother[1]	0.37	0.47	0.34
Sexual outcomes			
All participants:			
r between function and bother[1]	0.80	0.65	0.77
% more bothered by function[2]	1.0	0.7	0.7
% less bothered by function[2]	20.8	21.1	15.7
Married or living with a partner:			
r between function and bother[1]	0.81	0.65	0.79
% more bothered by function[2]	1.2	0.8	0.8
% less bothered by function[2]	21.2	21.2	15.7
Living alone:			
r between function and bother[1]	0.76	0.67	0.64
% more bothered by function[2]	0.0	0.0	0.0
% less bothered by function[2]	17.1	22.9	14.3

[1] All p-values <0.05.

[2] Defined as ≥2 times the value of a minimally important difference in the urinary (9) and sexual domain (12).[16, 17]