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A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings

Neena Agarwala
University of Nebraska Medical Center
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ABSTRACT

OBJECTIVE: A randomized prospective comparison of two synthetic mid-urethral tension-free slings was undertaken at a university hospital to evaluate clinical efficacy, complication rates, and ease of procedure and training of residents.

METHODS: Between January 2004 and September 2005, 96 women with stress urinary incontinence were consecutively assigned to Gynecare TVT® or Boston Scientific Lynx® mid-urethral slings (n=48 in each group) at the University of Nebraska Medical Center. Both groups were similar in mean age, parity, weight, preoperative post-void residual, cystometric capacity, flow rate, and urethral closure pressures. Postmenopausal status and previous incontinence surgery rates were also comparable. Intraoperative complications, ease of trocar placement, postoperative voiding difficulties, subjective and objective cure rates, and postoperative interventions were assessed. During statistical analysis, $p<0.05$ was used as cut-off for significance.

RESULTS: Half of the patients in both groups underwent multiple procedures. There were two (4%) trocar injuries with the TVT and three (6%) with the Lynx (p=.21). Early postoperative voiding dysfunction was 21% (10 patients) for the TVT group versus 15% (7 patients) for the Lynx ($p<0.001$), whereas prolonged catheterization for two weeks was similar at 4% (2 patients) for both. UTI rate for the TVT was 10% (5 patients) and 13% (6 patients) for Lynx (p=0.02). Subjective cure rates were 94% (45 patients) and 92% (44 patients), respectively (p=.08). Urethral closure pressure <14 cm H_2O was the identifiable risk for objective failure. Objective cure rates were 96% (46 patients) for the TVT and 94% (45 patients) for the Lynx (p=.12), suggesting that some subjective failure was likely due to de novo bladder overactivity. One sling in the Lynx group was removed for skin cellulites, and one sling slit in TVT group was removed for voiding dysfunction due to duplicated ureter on the left side.

CONCLUSION: Despite similar efficacy, complication rates, and failure rates, the incidence of postoperative voiding difficulties was better with Lynx, due likely to the mid-urethral seal. However, it was difficult to place the Lynx trocar in patients with prior surgeries, probably due to the blunt needle and notch. An increased rate of vaginal graft exposure was seen with the Lynx. Residents favored the Lynx trocar because of its light weight and greater stability.

KEYWORDS: TVT, Lynx, Synthetic mid-urethral tension-free slings

CORRESPONDENCE: Neena Agarwala, University of Nebraska Medical Center, Omaha, NE 68198, nagarwala@unmc.edu

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original study

A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings

OBJECTIVES

The purpose of this prospective randomized study was to compare the efficacy, intraoperative and postoperative complication rates, and ease of procedure and training for two synthetic mid-urethral slings in patients with stress urinary incontinence.

BACKGROUND

Urinary Incontinence affects 10-60% of women living in communities and at least 50% of women living in nursing homes [1]. The prevalence of urinary incontinence increases with age and peaks after menopause [2]. The most common type of incontinence is urodynamic stress incontinence, and the most severe type of incontinence is due to the sphincteric deficiency that occurs with advanced age [3].

In an evidence-based medicine era, health care professionals are obligated to carefully evaluate the evidence supporting their practice. For many aspects of medicine, including choice of surgery for the correction of incontinence, evidence is scant and of poor quality. Over 200 procedures to cure incontinence have been described in the medical literature, creating a level of dissatisfaction among surgeons [4].

Surgical treatments for stress incontinence include retropubic suspensions and sling placements. The basic goal of these procedures is to suspend, stabilize, and support the anterior vaginal wall, along with the bladder neck and proximal urethra, in an intra-abdominal location. Prevention of descent and placement of a suburethral compressive force allows for coaptation of the urethra and prevents leakage with increased intra-abdominal stress. The sub-urethral sling procedure involves placing a sling of either artifical or autologous tissue beneath the urethra and suspending the sling to various structures in the abdominal wall or retropubic space. The choice of material includes autologous fascia (rectus or fascia lata), vaginal wall, exogenous natural tissues (bovine, porcine, or cadaveric), and synthetic materials (mersilene tape, polytetrafluoroethylene (Gore-Tex®), marlex mesh, Teflon®, or silastic) [4]. The large diversity of sling materials and surgical techniques make evaluation of any one procedure difficult.

With the advent of tension-free vaginal tape procedures, surgical correction for stress urinary incontinence has become significantly less invasive without compromising efficacy [5,6]. Retropubic colposuspension was considered to be the gold standard treatment for stress urinary incontinence, with cure rates up to 90%, until several comparative trials have shown the tension-free sling procedure to have greater cure rates and less morbidity even compared to laparoscopic Burch colposuspension [7,8].

The tension-free tape procedure was developed as a minimally invasive sub-urethral sling procedure first reported by Ulmsten *et al.* in 1996 [9]. A narrow strip of polypropylene mesh is placed at the mid urethra to compensate for the impairment of the pubourethral ligaments [10]. The tape is thought to work by providing a pubourethral neoligament. An increase in intra-abdominal pressure results in kinking at the mid urethra and prevents urine loss [11]. Its first efficacy report at 3 years showed an 86% cure rate, which was comparable to other incontinence procedures [12].

The success of the tension-free tape has led to a flood of products with slight variations in the mesh or trocar assembly. Long-term data is available for Gynecare TVT® (manufactured by Ethicon Inc.), but not for many other available products. TVT has the advantage of being the first product on the market with the most experience. Boston Scientific developed a similar sling later, Lynx®, with the advantage of improving on the existing product. Do the changes really benefit, change the efficacy, or alter the safety profile of the slings? Both are monofilament, Type I, macroporous polypropylene meshes that allow macrophages to enter the pores causing rapid incorporation of fibroblasts and angiogenesis, thus decreasing the risk of infection [13]. The open weave PROLENE™ mesh also has unique biomechanical properties with low stiffness and low resistance to deformation [14], which may be the reason for its low risk of erosion. We wondered if the heat sealed edges in the Lynx system increased its resistance to deformation, thus increasing the risk of erosion.

Early work during the development of the tension-free sling concept showed that the technique of sling placement and the sling material were both important in avoiding complications with synthetic slings [15,16], but the sling material itself is of paramount importance [9]. All midurethral slings are not the same. Comparisons of TVT and SPARC™ systems have shown a significantly lower cure rate for SPARC [17], and our own experience comparing the TVT to the Stratasis TF® sling system showed a decline in cure rate over time using the Stratasis sling [18]. Even though one study comparing monofilament and multifilament tapes showed no differences [19], it appears that comparing these systems is the only way to prove efficacy.

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To our knowledge, there have been no studies comparing these two particular sling systems for the surgical treatment of stress urinary incontinence in women. Therefore, we decided to compare the TVT and the Lynx slings by prospectively randomizing patients into the two groups to compare efficacy, complication rates, and ease of teaching in a residency program.

MATERIALS AND METHODS

All patients seen at the Urogynecology Clinic at the University of Nebraska Medical Center between January 2004 and September 2005 who met the criteria for stress incontinence surgery were included. Patients were included if they had stress incontinence by history, demonstrated urodynamic stress incontinence, a positive cough stress test on simple bladder filling, and urethral mobility greater than 10 degrees or intrinsic sphincteric deficiency. Patients with plans for future pregnancy were not given the surgery option. Concurrent surgeries were performed in patients with other prolapses. All patients received brochures for both sling systems along with an explanation of the study, and a procedural informed consent was obtained.

Approximately 35% of the patients in both groups had had prior incontinence surgery, and more than half of the patients also underwent other surgical procedures for correction of their prolapse or removal of the uterus in conjunction with the sling procedure. Concurrent surgeries included 12 laparoscopic hysterectomies in the TVT group and 14 in the Lynx, laparoscopic vault suspensions or sacrocolpopexies in 10 of the TVT patients and 7 of the Lynx, 4 colpocleisis procedures with the TVT and 6 with the Lynx, posterior repairs in 18 of the TVT group and 14 with the Lynx, and 1 anterior repair in each group.

Concomitant Procedures	TVT group	Lynx group
Laparoscopic Hysterectomy	12	14
Laparoscopic Vault Support	10	7
Colpocleisis	4	6
Posterior repair	18	14
Anterior repair	1	1

Patients had preoperative and 6-week postoperative history and physical examination, cough stress test, post-void residual determination, and urine culture. Preoperatively, a cotton swab test, a uroflowmetry, and a complex multichannel cystometry were also performed to confirm diagnosis, to further delineate the bladder and urethral function, and to assess complex and neurogenic causes of urinary incontinence and voiding disorders. Preoperative work-up included a urogenital distress inventory and incontinence impact questionnaire along with a urogynecological exam. The diagnosis of genuine stress incontinence was made by observable leakage of urine with stress and without detrusor activity during cystometry.

Patients were scheduled for surgery by the scheduling secretary without regards to their profile. In the operating room, the patients were consecutively assigned either TVT or Lynx slings based on odd or even numbers. At the end of the study period, patient characteristics and intraoperative and postoperative complications were compiled and analyzed. Residents conveyed their preference by answering the questionnaire below, and any issues related to the individual device handling during the surgeries were written down after each procedure.

Resident HOIV Questionnaire: Total score of 5
1. Which sling needle was easy to pass?
2. Which sling needle was easy to handle and more stable?
3. Which sling procedure was technically easier?
4. Which device would you pick in your practice?
5. Which device was easier to place in scarred tissue?

Standard operating technique using the abdominal guides and abdominal approach was used in all cases. The mid-urethral vaginal mucosa was infiltrated with local anesthetic, dissection was done laterally, two suprapubic stab incisions were made 2 cms from midline on either side, and the retropubic space was injected with diluted local anesthetic. A bladder deflector was used in all cases, trocars were passed using abdominal guides, and a cystoscopy was performed. The sling was then attached and pulled, and a second cystoscopy was always performed to evaluate the sling dynamics. A crede test was done for fine adjustment of the tape, followed by removal of the plastic sheaths and trimming of the sling. The vaginal mucosa was sutured closed, and the suprapubic incisions glued. Patients without additional procedures attempted voiding the same day, while patients with additional procedures had Foley catheters overnight.

Data analysis was done for the following parameters: intraoperative complications, early and late postoperative complications, any interventions, and subjective and objective changes in urinary incontinence. Ease of resident training was assessed by the level of difficulty in passing the sling trocars. Residents also provided feedback on their experiences with

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both the devices and what they liked or disliked about each system.

Intraoperative and immediate postoperative complications of stress incontinence surgery include direct injury like cystotomy, hemorrhage, bowel injury, wound complications, retention or voiding difficulty, and urinary tract infection. A cystoscopy was performed during each procedure to verify ureteral patency and absence of sling or stitches in the bladder. Chronic complications of stress incontinence surgery are mostly related to voiding dysfunction and urge symptoms and were assessed by postoperative urogenital distress and incontinence impact questionnaires.

Postoperative voiding dysfunction was defined as inability to void or high post-void residual (PVR>200cc) at the time of discharge from hospital. Subjective cure was assessed at six weeks postoperatively and was defined as the absence of any symptoms of involuntary loss of urine with stress or valsalva at the time of postoperative evaluation. Patient satisfaction by either complete dryness or more than 90% improvement in stress incontinence episodes as perceived by the patient was also noted on postoperative questionnaire using Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ- 7) (Appendix 1 and 2). Objective cure was defined as the absence of involuntary loss of urine with standing stress after simple filling of the bladder with 250cc water. The ability or inability to demonstrate stress incontinence during simple bladder filling and cough stress test correlates highly with the presence or absence of urodynamic stress incontinence [20,21]. Therefore, this parameter was chosen as a postoperative objective verification of success or failure. Follow-up at 6 months, 12 months, and 18 months was only subjective in nature.

Outcomes are presented as a mean (standard deviation) or as a frequency (percent). Statistical analysis with $p<0.05$ was used as cut-off for significance.

RESULTS

Table 1 compares the patient characteristics of the two groups. Ninety-six patients, 48 (50%) using TVT and 48 (50%) using Lynx, were identified. Both groups were similar in mean age (64, 65), parity (2.6, 2.8), and weight in kg (83.7, 85.8). The mean preoperative PVR in cc (63, 54), maximum cystometric capacity in cc (380, 396), and functional urethral length in cm (2.4, 2.5; p=0.17) were also comparable. Forty-four (92%) TVT

Table 1. Patient characteristics
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Patient characteristics	TVT group (n=48)	Lynx group (n=48)	p
Age (y) (mean ± SD)	64 ± 10.2	65 ± 11.1	.57
Parity (mean)	2.6	2.8	.16
Weight (kg) (mean ± SD)	83.7 ± 22	85.8 ± 20	.93
Body Mass Index (kg/m2) (mean ± SD)	27.8 ± 6.3	29.4 ± 5.9	.86
Postmenopausal	44 (92%)	43 (90%)	.13
Primary surgery	31 (65%)	32 (67%)	.81
Prior surgery for incontinence	17 (35%)	16 (33%)	.12
Sling procedure only	22 (46%)	21 (44%)	.37
Sling with other procedures	26 (54%)	27 (56%)	.63
Preoperative characteristics			
Duration of incontinence (years) (mean ± SD)	5.2 ± 2.2	4.9 ± 3.4	.80
Frequency (>7 times/ day)	33 (69%)	31 (65%)	.90
Nocturia (>2 times/ night)	18 (38%)	20 (42%)	.37
Quality of life assessment (/10)	8.6	8.5	.89
Emotional impact (/10)	8.8	8.7	.63
Urodynamic characteristics (mean)			
Maximum cystometric capacity (cc)	380	396	.68
Functional urethral length (cm)	2.4	2.5	.17
Post void residual (cc)	63	54	.37
Maximum urethral closure pressures (cm H2O)	42	50	.15
Maximum flow rate (cc)	22	23	.07
MUCP <25 cm H2O (ISD)	6 (12.5%)	5 (10.4%)	.23

patients were postmenopausal compared to 43 (90%) Lynx patients (p=0.13). Seventeen (35%) TVT cases had previous incontinence surgeries compared to 16 (33%) Lynx cases (p=0.12). Preoperative maximum urethral closure pressures were 42 cm of H_20 for TVT patients and 50 cm of H_2O for Lynx patients (p=0.15), and maximum flow rates were 22 cc/sec for TVT and 23 cc/sec for Lynx (p=0.07). Multiple procedures were performed in 26 (54%) TVT cases and 27 (56%) Lynx cases.

Table 2 is a comparison of the complications and results from the two groups. Intraoperative injuries were higher in the Lynx group with 3 (6%) trocar injuries versus 2 (4%) for TVT. In general, the trocar injury rate is higher than most reported data due to the resident teaching and changing of residents every four months. Four of the five trocar injuries occurred in patients who had had prior incontinence procedures. This is still comparable to the reported rate of 5.4% (0-23.1%) [22].

The incidence of early postoperative voiding dysfunction was higher in the TVT group (10 patients, 21%) compared to Lynx (7 patients, 15%) (p<0.001). Patients in both groups that had early voiding dysfunction were younger than 58 years in age. Voiding dysfunction resolved in all but one patient in each group, and both of them described some hesitancy with a full bladder. The need for prolonged or self-catheterization for 12-14 days was similar (2 patients, 4%) for both groups. One patient had a vaginal Prolift® (total vaginal mesh) procedure, and the other was a complex and large prolapse in the TVT group. In the Lynx group, one patient had four prior incontinence procedures and the other was a simple hysterectomy with the sling. The rate of urinary tract infections was 10% (5 patients) with the TVT versus 13% (6 patients) with the Lynx (p=0.12).

Table 2. Complications and results
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Complications and results	TVT group (n=48)	Lynx group (n=48)	P
Trocar injury	2 (4%)	3 (6%)	.21
Hemorrhage	0 (0%	0 (0%)	
Bowel Injury	0 (0%)	0 (0%)	
Postoperative voiding dysfunction (retention/ hesitancy/poor stream)	10 (21%)	7 (15%)	<0.001
12-14 days of catheterization	2 (4%)	2 (4%)	.08
Postoperative UTI	5 (10%)	6 (13%)	.12
Interventions			
Removal of sling	0 (0%)	1 (2%)	.43
Sling slit	1 (2%)	0 (0%)	.58
Vaginal sling exposure	0 (0%)	2(4%)	.45
Subjective cure	45 (94%)	44 (92%)	.08
Objective cure	46 (95.8%)	45 (93.8%)	.07
Patient satisfaction	44 (92%)	44(92%)	.12
Failure	3 (6%)	4 (8%)	.25
New onset detrusor instability	1 (2%)	1 (2%)	.99

The Lynx group had one patient whose sling was removed due to a skin cellulitis five days postoperatively. This patient had received prior radiation to the pelvis and developed laparoscopy site cellulitis, which appeared to be spreading. The sling was removed to avoid any possible tracking of infection via a foreign body. One patient in the TVT group had her sling slit at 10 days due to voiding dysfunction. This patient had duplicated ureters on the left side. The second ureteral orifice was close to the UV junction and created a flap like effect with the sling. After slitting the sling towards the left side, her voiding became completely normal with no recurrence of stress incontinence.

Two patients in the Lynx group had a vaginal sling exposure. One healed spontaneously, and the other required a small graft excision and mucosal closure. No exposures were seen with the TVT group. Could this be due to the heat sealed edges and higher resistance to deformation?

In the TVT group, the subjective cure rate was 94% (45 patients) compared to 92% (44 patients) in the Lynx group. 82% of the TVT group and 78% of the Lynx group patients reported complete dryness, and an additional 12% with the TVT and 14% with the Lynx reported more than 90% improvement. If the patient whose sling was removed due to cellulitis is withdrawn from the statistics, the 3 failures in each group were severely low pressure urethras (<25 cm H2O) with minimal hypermobility and were older than 68 years of age. Objective cure rates were 96% (46 patients) with the TVT and 94% (45 patients) with the Lynx. These rates are again quite identical if the sling removal is not included, suggesting that the subjective incontinence was likely overactivity of the bladder rather than stress leakage.

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The residents favored the Lynx sling, giving it greater scores for ease, technicality, and stability. In cases where the tissue was scarred from prior surgeries, Lynx was thought to be harder to pass and TVT sling was preferred.

Score - Resident HOIV Questionnaire: Total score of 5/resident	TVT	Lynx
1. Which sling needle was easy to pass?	0	3
2. Which sling needle was easy to handle and more stable?	1	2
3. Which sling procedure was technically easier?	1	2
4. Which device would you pick in your practice?	1	2
5. Which device was easier to place in scarred tissue?	3	0
Total:	6	9

DISCUSSION

Tension-free slings, a minimally invasive surgical technique for stress urinary incontinence, have been increasing in popularity. They have truly revolutionized anti-incontinence surgery and have changed practice patterns of most gynecologists, urologists, and uro-gynecologists. The modifications and theoretical improvements by different companies will definitely have further impact on the success and failure of this procedure. Therefore, it is imperative to take a closer look at these changes and alterations to evaluate their efficacy and risks. This study has done a small task of comparing two types of products on the market, but there are many more available. Each physician needs to look at each product with a critical eye, search the literature for established data, and adopt the product on its merits.

In accordance with the NIH's emphasis on the evaluation of subjective and objective efficacy, adverse events, and unwanted symptoms in the treatment of urinary incontinence, we chose an optimal surgical outcome as our primary outcome [23]. In this prospective, randomized comparison of two varieties of synthetic mid-urethral slings, the two slings had similar efficacy, complication, and failure rates. We would expect such a result with all the different types of mid-urethral slings since the mechanism of action should be the same. Several different tension-free sling kits are available that use different trocars or mesh types. These may have different rates of complication or efficacy than those found in this study. It is important to note that the results from this study may not be transferable to tension-free slings beyond the two specific devices evaluated in this study.

The principal strengths of this single-center clinical trial are the use of standardized and validated outcome measures, a high follow-up rate, and a single surgeon performing the operations. Major limitations include the use of an unblinded clinical examiner to perform follow-up evaluations, a single center evaluation, and short follow-up period. Additionally, since a majority of the patients had concurrent pelvic reconstructive surgery, the true postoperative assessments may have been compromised by the additional surgery. Since the complication rates, adverse events, and unwanted symptom rates were not excessively high, we believe that this type of population is indeed the ideal population to be studied and additional reconstructive surgery does not impact the efficacy of the tension-free slings.

Subjective and objective continence was similar for both the sling types. Approximately 95% of participants in both treatment groups had resolution of their stress urinary incontinence symptoms and nearly 80% reported complete dryness with an additional 12% reporting improvement subjectively. Stress incontinence surgery success rates vary depending on the outcome measures that are studied [24]. It is, therefore, best to use both validated patient reported measures and objective tests, like stress tests and urodynamics in the office. Our subjective cures were closer to the objective measures likely due to a single surgeon clinic and operating technique.

Postoperative voiding dysfunction was the only statistically significant difference between the two sling types. The incidence of postoperative voiding difficulties was slightly better with Lynx compared to TVT, probably due to the mid-urethral heat sealing and stabilization of the tape. A higher incidence of vaginal graft exposure was seen with the Lynx group as well, probably due to the same heat sealed region and greater stiffness. Per resident questionnaire results, it was slightly difficult to place the Lynx trocar in patients with prior surgeries, likely due to the blunt nature of the needle and a small tissue drag secondary to the notch at the needle end. In general, though, residents favored the Lynx trocar due to its light weight and greater stability.

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Though urethral pressure profiles have not met the criteria for a useful diagnostic test due to irreproducibility and non-standardization [25], a low urethral closure pressure does indicate a deficient sphincter and, therefore, a lower success rate with a tension-free sling. Increasing age also appears to be an independent risk factor for lower urethral closure pressures and therefore lower success [26].

Trocar injury with bladder perforation seems to be predictably higher in scarred retropubic spaces, and early postoperative voiding dysfunction seems more prevalent in younger patients. It was our observation that anxiety played a significant role in early voiding dysfunction and nearly disappeared by two weeks in all but 2 patients. Severe complications, like hemorrhage and vascular and bowel injury, are rare and were not encountered [27-30].

Polypropylene mesh in general seems to be very well received by the body with low rates of rejection and infection. The risks of needle placement, namely bladder perforation and bowel or vascular injury, are small but well recognized and must always be kept in mind. Ways to reduce them further must be advocated.

In conclusion, both sling types were similar in efficacy for the treatment of stress urinary incontinence in women with and without pelvic organ prolapse with 1-2 years of follow up. Intraoperative complications were similar for the two types, though Lynx resulted in lesser postoperative voiding dysfunction. Larger studies with longer follow-ups are needed to compare the less common complications and long-term durability. Additional studies need be performed to compare all the different sling kits on the market.

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Appendix 1. Urogenital Distress Inventory Questionnaire

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Urogenital Distress Inventory (UDI/6)

	Not at All	Slightly	Moderately	Greatly
Do you have:				
1. Frequent urination?				
2. Urine leakage related to the feeling of urgency?				
3. Urine leakage related to physical activity, laughing or coughing?				
4. Small amounts of urine leakage (drops)?				
5. Difficulty emptying your bladder?				
6. Pain or discomfort in the lower abdominal or genital area?				
Total	__	__	__	___

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Appendix 2. Incontinence Impact Questionnaire - Short From IIQ-7 (Pre and Post Surgery Questionnaire)

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Incontinence Impact Questionnaire – Short Form IIQ-7 (Pre and Post Surgery Questionnaire)

Some people find that accidental urine loss may affect their activities, relationships, and feelings. The questions below refer to areas in your life that may have been influenced or changed by your problem. For each question, circle the response that best describes how much your activities, relationships, and feelings are being affected by urine leakage.

Has urine leakage affected your…

	Not at All	Slightly	Moderately	Greatly
1. Ability to do household chores (cooking, housecleaning, laundry)?	0	1	2	3
2. Physical recreation such as walking, swimming, or other exercise?	0	1	2	3
3. Entertainment activities (movies, concerts, etc.)?	0	1	2	3
4. Ability to travel by car or bus more than 30 minutes from home?	0	1	2	3
5. Participation in social activities outside your home?	0	1	2	3
6. Emotional health (nervousness, depression, etc.)?	0	1	2	3
7. Feeling frustrated?	0	1	2	3

Items 1 and 2 = physical activity
Items 3 and 4 = travel
Item 5 = social/relationships
Items 6 and 7 = emotional health

Scoring. Item responses are assigned values of 0 for "not at all," 1 for "slightly," 2 for "moderately," and 3 for "greatly." The average score of items responded to is calculated. The average, which ranges from 0 to 3, is multiplied by 33 1/3 to put scores on a scale of 0 to 100.

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