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The role of preoperative urodynamic testing in stress-continent women undergoing sacrocolpopexy:

the Colpopexy and Urinary Reduction Efforts (CARE) randomized surgical trial

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Abstract

The aim of this study is to describe results of reduction testing in stress-continent women undergoing sacrocolpopexy and to estimate whether stress leakage during urodynamic testing with prolapse reduction predicts postoperative stress incontinence. Three hundred twenty-two stress-continent women with stages II—IV prolapse underwent standardized urodynamics. Five prolapse reduction methods were tested: two at each site and both performed for each subject. Clinicians were masked to urodynamic results. At sacrocolpopexy, participants were randomized to Burch colposuspension or no Burch (control). *P*-values were computed by two-tailed Fisher's exact test or *t*-test. Preoperatively, only 12 of 313 (3.7%) subjects demonstrated urodynamic stress incontinence (USI) *without* prolapse reduction. More women leaked after the second method than after the first (22% vs. 16%; $p = 0.012$). Preoperative detection of USI *with* prolapse reduction at 300ml was pessary,

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6% (5 of 88); manual, 16% (19 of 122); forceps, 21% (21 of 98); swab, 20% (32 of 158); and speculum, 30% (35 of 118). Women who demonstrated preoperative USI during prolapse reduction were more likely to report postoperative stress incontinence, regardless of concomitant colposuspension (controls 58% vs. 38% ($p = 0.04$) and Burch 32% vs. 21% ($p = 0.19$)). In stress-continent women undergoing sacrocolpopexy, few women demonstrated USI without prolapse reduction. Detection rates of USI with prolapse reduction varied significantly by reduction method. Preoperative USI leakage during reduction testing is associated with a higher risk for postoperative stress incontinence at 3 months. Future research is warranted in this patient population to evaluate other treatment options to refine predictions and further reduce the risk of postoperative stress incontinence.

Keywords

Occult incontinence; Urodynamics; Prolapse reduction; Sacrocolpopexy

Introduction

Stress-continent women with advanced pelvic organ prolapse may develop signs and symptoms of stress incontinence following prolapse treatment. This is believed to be due to correction of anatomic urethral kinking or obstruction from the advanced prolapse [1]. Preoperative urodynamic testing with prolapse reduction in patients with advanced pelvic organ prolapse is commonly used to diagnose occult stress incontinence and in an attempt to predict which patients are likely to benefit from an incontinence procedure at the time of prolapse repair [1–5].

The predictive ability of preoperative urodynamic testing in patients with advanced prolapse is variable. Liang et al. found that none of 30 women that did not leak preoperatively when uterine prolapse was reduced with a pessary developed postoperative stress incontinence and therefore recommended no anti-incontinence procedure in this group [6]. Similarly, in a retrospective review, Klutke and Ramos reported that none of 70 women without “reduced stress incontinence” developed leakage after prolapse surgery [7]. In Liang’s study, 53% of those that leaked during preoperative testing and did not receive an anti-incontinence surgery developed leakage postoperatively, compared to none of the 32 women that underwent a tension-free vaginal tape. Of note, in this study, women were excluded that had a prior hysterectomy or anti-incontinence surgery. In another series of 24 women with grade 3 or 4 prolapse without stress incontinence, 58% leaked during reduction testing with a vaginal pessary. After undergoing a pubovaginal sling, 14% of these had new onset stress incontinence [8]. However, as none of these studies randomized women to either an incontinence procedure or no incontinence procedure, the ability to critically examine the predictive value of urodynamic testing was limited.

The Pelvic Floor Disorders Network (National Institute of Child Health and Human Development) conducted the Colpopexy and Urinary Reduction Efforts (CARE) randomized surgical trial [9] in 322 stress-continent women undergoing abdominal sacrocolpopexy for stages II—IV pelvic organ prolapse. Based on a planned interim analysis, the CARE trial ended early because of a significant reduction in postoperative stress incontinence in the Burch group with no difference in other lower urinary tract symptoms or serious adverse events between groups. However, nearly a quarter of the women still developed stress incontinence despite undergoing the additional Burch, with approximately one in 20 experiencing bothersome stress incontinence. Stress incontinence symptoms accounted for the majority of the difference between groups.

The CARE trial provided a unique opportunity to assess the value and predictive ability of standardized preoperative urodynamic testing in a population of women with advanced prolapse but without symptoms of stress incontinence. In an attempt to provide clinicians with further information regarding occult incontinence, we sought to describe urodynamic stress incontinence with and without prolapse reduction using five prolapse reduction methods and to determine the ability of positive preoperative urodynamic testing to predict postoperative stress incontinence.

Materials and methods

The full methods of the CARE trial [10] and primary outcomes 3 months after surgery [9] have been previously published. Women were eligible if they planned sacrocolpopexy for stages II—IV pelvic organ prolapse [11] and they answered “never” or “rarely” to six of the stress incontinence questions from the Medical, Epidemiological, and Social Aspects of Aging questionnaire [12]. The study was approved by the Institutional Review Boards at the ten clinical centers and the data coordinating center (DCC). Subjects were randomly assigned by the DCC to abdominal sacrocolpopexy with or without Burch colposuspension. Randomization was stratified by surgeon and planned paravaginal repair (given its potential impact on continence) [13,14].

All subjects underwent preoperative standardized assessment of pelvic organ prolapse, Q-tip testing [15], and multichannel urodynamic testing. Resting and straining angles were recorded. Urethral hypermobility was defined as resting or straining angle >20° from the horizontal.

Surgeons were blinded to results of urodynamic testing, including the cough stress test with prolapse reduction. Each clinical site was assigned two methods of prolapse reduction that they used throughout the trial (manual, large cotton swab, ring forceps, pessary, and split speculum). All methods entailed reducing the prolapse to the extent expected by abdominal sacrocolpopexy. Pessary reduction used a ring pessary with support, with the size chosen by the research staff to be loose-fitting but large enough to be retained during Valsalva and cough provocation.

After uroflowmetry, subjects underwent a standardized non-fluoroscopic cystometrogram with external water pressure transducers ≤8 French while seated at a 45° angle. A rectal catheter was used to estimate intra-abdominal pressure. The catheters were zeroed to atmosphere at the level of symphysis pubis. The bladder was filled with saline at 50ml/min. Detrusor pressure was confirmed to be between 0 and 5cmH_2O during early filling or the ports were flushed and the equipment was re-zeroed.

At 300ml or maximum bladder capacity, subjects underwent a series of three Valsalva leak point pressures (VLPP) and a series of three cough leak point pressures (CLPP) without prolapse reduction. CLPPs were performed by asking the subject to cough gently, moderately, and then more forcefully, each time recording simultaneous pressure and whether urine loss occurred. VLPPs and CLPPs were calculated as the relative increase over baseline ([maximum intravesical pressure at leakage] minus [baseline intravesical pressure]). Pressures were allowed to return to baseline before the next Valsalva or cough.

Subjects then underwent prolapse reduction testing at 300-ml bladder volume. Each site used the same two methods for prolapse reduction at that particular site throughout the trial. The sequence of the two prolapse reduction methods at each site was assigned according to even and odd dates. The prolapse was reduced with the first and then the second of two methods assigned to each clinical site, and Valsalva and cough stress testing was performed for each method. Women were considered to have urodynamic stress incontinence with reduction (that is, a positive reduced stress test) if they leaked urine at 300-ml volume (or maximal capacity,

if less) with one or both of the reduction methods. After reduction testing at 300ml, the second prolapse reduction method was left in place and bladder filling was resumed until maximum capacity (when the subject could no longer delay a trip to the bathroom). The Valsalva and cough stress testing was repeated at maximum capacity with only the second prolapse reduction method. If the subject had not leaked following Valsalva and cough testing at maximum capacity, the transurethral catheter was removed and the subject was instructed to Valsalva and cough with maximal effort. Any urine leakage was recorded. Regardless of whether leakage occurred, the prolapse reduction method was removed and the transurethral catheter was replaced for the pressure-flow voiding study.

As in the primary outcome paper, postoperative stress incontinence (the stress endpoint) was defined 3 months after surgery, by the presence of at least one of the following three components: (1) positive stress incontinence symptoms ("yes" to one or more of three questions in the Pelvic Floor Distress Inventory (PFDI) [16] stress incontinence subscale, assessing leakage with coughing, sneezing, or laughing; physical exercise; and lifting or bending over); or (2) positive sign (positive stress test at 300ml or maximum bladder capacity, whichever was less, supine and standing with Valsalva and cough provocation); or (3) any treatment for stress incontinence after the index surgery [10].

Five different methods of prolapse reduction were used. Secondary to early discontinuation of the trial, the reduced number of patients did not allow formal statistical testing comparing outcomes of the five methods of reduction testing. In order to determine whether reduction testing may perform better in identifying those women in the Burch group who developed more severe symptoms, we defined these symptoms as moderate or severe bother of the stress incontinence subscale questions of the PFDI and/or treatment for stress incontinence within the first three postoperative months. The predictive value of prolapse reduction testing on postoperative stress incontinence for women in the no Burch and Burch groups is described to try to determine whether a group of women at risk for leakage even after a Burch colposuspension could be identified. Postoperative stress incontinence (that is, failure of prevention) rates were compared using Fisher's exact test (two-tailed) and *t*-test (two-tailed). The rates of urodynamic stress incontinence were compared between the first vs. second method of reduction by applying Fisher's method of combining independent tests to comparisons of each pair of methods in the cases where they differed.

Results

The CARE trial randomized 322 women between March 2002 and February 2005 and discontinued enrolling subjects after the first planned interim analysis because of significant benefit in the Burch group. Of those enrolled, 157 were randomized to abdominal sacrocolpopexy plus Burch colposuspension (Burch group) and 165 were randomized to abdominal sacrocolpopexy without Burch colposuspension (no Burch group). Baseline characteristics for subjects randomized were similar in both groups (see Table 1).

Urodynamic stress incontinence without prolapse reduction was infrequent, being noted in only 12 of 313 (3.7%) women. Overall, at 300-ml bladder volume, 27% (78/293) of subjects leaked during reduction testing with either the first or the second assigned method. More women leaked after the second method of reduction (65/291 = 22%) than after the first (47/293 = 16%; $p = 0.012$). Significant differences were noted in the detection of urodynamic stress incontinence with prolapse reduction among the various methods studied. Table 2 summarizes results by reduction method.

Overall, urodynamic stress incontinence with barrier reduction was diagnosed in 19% of subjects with pessary having the lowest rate of detection (6%) and speculum the highest (30%).

The test characteristics of the prolapse reduction methods to predict postoperative stress incontinence were evaluated in the no Burch group (controls). Of the five methods assessed, the swab technique had the highest positive predictive value (PPV) in controls (79%) for postoperative leakage, but this does not differ statistically from the other rates. All other methods had PPVs ranging from 50% to 55% (Table 3).

In the Burch group, test characteristics of prolapse reduction for all five methods combined were as follows: sensitivity 33%, specificity 83%, positive predictive value 37%, and negative predictive value of 80%. The test characteristics varied by each reduction method (Table 4). Overall, the prolapse reduction tests had low sensitivities and high specificities. The individual reduction methods had similarly low positive predictive values but high negative predictive values. Positive reduction testing was predictive in 39% (12/31) of women with moderate to severe incontinence. Retesting at maximum capacity, rather than 300ml volume, did not yield an improved prediction.

With any reduction method, postoperative stress incontinence was higher after positive preoperative urodynamic testing. In the control group (no Burch), postoperative stress incontinence occurred in 58% of subjects who leaked during reduction testing, compared to 38% with negative testing. In the Burch group, positive leakage on urodynamic testing with prolapse reduction was associated with higher postoperative stress incontinence, 32%, compared to 21% in subjects with negative leakage on preoperative urodynamic testing with prolapse reduction. However, Burch colposuspension reduced postoperative stress incontinence in both subjects who leaked during urodynamic testing at 300ml and those who did not (see Table 5). Similar findings were noted at maximum capacity (see Table 6).

We next evaluated the minimum CLPP and VLPP to determine if LPPs obtained during prolapse reduction were predictive of postoperative stress continence status. As leak point pressures are only available from subjects who demonstrate urodynamic stress incontinence with prolapse reduction and as the trial was ended early, the study was not adequately powered to compare leak point pressures by reduction method. In the control (no Burch) group and at maximum cystometric capacity, the mean cough leak point pressure was significantly lower in the group that developed postoperative stress incontinence, 105 vs. 77cmH_2O ($p < 0.05$). However, a similar finding was not observed in the group that received a Burch (Table 7).

We also considered whether testing may perform better in identifying those that developed more severe symptoms, which we defined as moderate or severe bother of the stress incontinence symptoms and/or treatment for stress incontinence within the first three postoperative months. In the control (no Burch) group, the ability of the various reduction methods to predict moderate to severe stress incontinence ranged from poor to fair: from 7% (1/15) for the pessary to 35% (8/23) for the swab. In the Burch group, leakage during reduction testing predicted moderate to severe incontinence ranging from 20% (1/5) in both the swab and pessary to 56% (5/9) for the speculum. Retesting at maximum capacity, rather than 300ml volume, did not improve results.

Finally, we also evaluated whether the predictive value of reduction testing in women in the Burch group differed according to previous surgical history. As 72% of our subjects already had a hysterectomy, we could not examine whether predictive testing differed in women with a uterus preoperative and who underwent a concurrent hysterectomy. We found no differences in either the rates of postoperative stress incontinence or in the predictive value of the preoperative reduction testing based on whether or not women in the Burch group had prior surgery. Similarly, no significant difference in postoperative stress urinary incontinence (SUI) based on the presence or absence of urethral hypermobility was noted (23% (30/129) vs. 13% (2/15); $p = 0.52$).

Discussion

The CARE trial demonstrated that adding a Burch colposuspension in stress-continent women undergoing sacrocolpopexy for prolapse significantly reduces postoperative stress incontinence by half [9]. We sought to determine in this population, whether preoperative urodynamics with prolapse reduction predicted postoperative continence status. We found that USI without prolapse reduction was so uncommon in patients with stages II—IV prolapse that the value of this particular test has limited significance. Clinicians may consider limiting their stress testing in patients with advanced prolapse to reduction testing.

Many methods have been described to reduce prolapse during cough stress testing. Rates of urodynamic stress incontinence with prolapse reduction (using various methods) reported in symptomatically continent women with prolapse range from 25% to 100% [1,4,8,17–19]. Rather than arbitrarily choosing one, we studied five common methods of prolapse reduction: manual, large cotton swab, ring forceps, pessary, and split speculum. Overall, we observed a slightly lower rate of urodynamic stress incontinence with prolapse reduction. We also found the diagnosis of urodynamic stress incontinence and the ability to predict postoperative incontinence to be markedly variable among five commonly used reduction methods. While some use pessary for reduction testing, we found this method to be the least likely to result in leakage during urodynamic testing and one of the least predictive ones. This may not be surprising, considering that pessaries increase the maximum urethral closure pressure and functional urethral length [20] and, in fact, are often used to treat stress incontinence [21].

Most studies that report rates of stress incontinence during reduction urodynamic testing do not report the predictive ability of that test in women who did not undergo continence procedures. The two studies that did correlate testing with postoperative outcomes came to opposite conclusions. Bergman and colleagues studied reduction testing with a pessary in women with prolapse without stress incontinence. The investigators divided subjects into two groups based on abdominal pressure transmission ratios (PTR). The 24 women with PTR less than 100% underwent a needle suspension procedure while none of 43 women with “adequate” abdominal pressure transmission ratios had a continence procedure. Since no patient in either group reported developed postoperative stress incontinence, the authors concluded that urodynamic testing can correctly identify women at risk of developing postoperative incontinence [22]. In contrast, Bump and colleagues [23] concluded that preoperative barrier testing was not useful in identifying women requiring urethropexy. The authors of a recent review [24] concluded that minimal evidence exists suggesting that patients with occult incontinence are at increased risk of postoperative stress incontinence and that, given this, we cannot counsel women about our ability to prevent postoperative incontinence or protect them from unnecessary procedures. Our data shed further light on this topic.

Overall, preoperative testing with prolapse reduction is not perfect as a significant percentage of women who did not leak during the preoperative testing had postoperative stress incontinence. The swab prolapse reduction method yielded the highest positive predictive value in the control group (no Burch). The swab’s improved predictive value may be explained by its ability to more closely approximate the effect on the vaginal apex of a sacrocolpopexy. However, a significant percent of patients that did not leak during preoperative testing with the swab technique developed postoperative incontinence, requiring further evaluation of this reduction method.

Ideally, reduction urodynamics would also predict which patients are likely to have persistent symptoms despite the Burch colposuspension and may require another procedure such as a sling. Overall, we found that women who leaked during preoperative reduction testing were more likely to have postoperative leakage in both the group that received a Burch and controls.

This finding helps counsel patients about their risk of postoperative stress incontinence and supports further investigation into whether slings would further improve continence status. Until such evidence becomes available, we are able to convey to patients that adding a Burch colposuspension is beneficial and roughly reduces the rate of postoperative stress incontinence by half whether or not urodynamic stress incontinence occurs during prolapse reduction.

The obvious clinical question raised by our results is: should we still recommend stress testing during urodynamics in women with prolapse? Reduction stress testing does help to identify women at higher risk of developing stress incontinence, whether or not they have a Burch. If this information prompts the surgeon to do something different (for example, a different prolapse operation or different anti-incontinence procedure), testing may be warranted. However, there is no evidence yet to suggest that another prophylactic procedure would produce better continence rates in these patients. It is unknown whether women at risk for leaking after a Burch may also be at risk of leaking after other procedures such as slings or whether such procedures have a risk profile similar to a Burch. Surgeons may use urodynamic information to counsel women but must also convey that a negative test does not preclude postoperative incontinence.

While we had initially planned to study whether values for leak point pressures might add to the predictive ability of the reduction stress tests, only 37% of women in the Burch group actually had urodynamic stress incontinence during prolapse reduction testing and thus we were not able to explore this fully. We found that women in the control (no Burch) group that developed postoperative stress incontinence had significantly lower mean cough leak point pressures, but this was only seen at maximum cystometric capacity. Clearly, studies with large numbers of women would be needed to evaluate leak point pressures with various reduction methods.

Our study population was limited to women without preoperative complaints of SUI. Therefore, we can not extrapolate our findings to women with advanced prolapse and SUI. Caution must also be advised in generalizing these results to other surgeries for prolapse and other anti-incontinence procedures. Although not specifically studied, based on clinical experience, surgeons believe that abdominal and vaginal surgeries place the vagina in different locations. Further research is needed to determine the utility of reduction testing in women undergoing vaginal surgery. Because we studied the impact of an intervention on preventing, rather than treating, stress incontinence, we evaluated outcomes 3 months postoperatively. Whether predictive testing has greater value in identifying women with stress incontinence more remote from surgery remains to be seen and will be reported as the duration of follow-up for subjects enrolled in the CARE trial increases.

In summary, neither doing preoperative reduction urodynamic testing nor adding a Burch colposuspension at the time of sacrocolpopexy can perfectly predict or prevent postoperative stress incontinence. Of the reduction methods we tested, the swab most closely predicted postoperative stress incontinence in women that did not have a Burch. Positive preoperative reduction testing in stress-continent women planning sacrocolpopexy and Burch colposuspension is associated with a higher risk for postoperative leakage and may identify a patient population worthy of further study to evaluate other treatment options to further reduce the risk of postoperative incontinence.

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Table 1

Baseline characteristics in CARE study population

		Burch, *N*= 157	Control, *N*= 165	*p*-value
Age (years)	Mean±SD	62.4±9.7	60.3±10.6	0.071
Race	White/Caucasian	151 (96.2%)	148 (89.7%)	0.13
	Black/African American	5 (3.2%)	12 (7.3%)	
	Hispanic	2 (1.3%)	7 (4.2%)	0.11
	Other	1 (0.6%)	5 (3.0%)	
Marital status	Married or living as married	120 (77.4%)	119 (72.1%)	0.30
Education	Less than high school	19 (12.1%)	8 (4.8%)	0.063
	Completed high school or equivalent	58 (36.9%)	67 (40.6%)	
	Some college or higher	80 (51.0%)	90 (64.1%)	
Health insurance	Private insurance	54 (38.8%)	71 (50.4%)	0.17
	HMO	17 (12.2%)	12 (8.5%)	
	Government assistance	48 (34.5%)	36 (25.5%)	
	Self pay and other	20 (14.4%)	22 (15.6%)	
Previous vaginal births	Median, range	3 (0–8)	3 (1–11)	0.43
Previous cesarean births	Median, range	0 (0–5)	0 (0–2)	0.35
Total previous births	Median, range	3 (1–10)	3 (1–11)	0.61
Prior surgery for incontinence		11 (7.1%)	11 (6.7%)	0.89
Prior surgery for prolapse		69 (44.2%)	57 (34.5%)	0.076
POP-Q stage	Stage II	19 (12.1%)	25 (15.2%)	0.53
	Stage III	105 (66.9%)	112 (67.9%)	
	Stage IV	33 (21.0%)	28 (16.9%)	

Table 2

Rates of urodynamic stress incontinence with various methods of prolapse reduction (Burch and no Burch groups combined, *n*= 322)

Prolapse reduction	**Preoperative leakage with reduction**[a]	
	N	**%**
All methods combined	112/584	19%
Pessary	5/88	6%
Manual	19/122	16%
Swab	32/158	20%
Forceps	21/98	21%
Speculum	35/118	30%

[a]There were two attempts at prolapse reduction stress testing per subject.

Table 3

Postoperative rates of stress urinary incontinence in the *no Burch group by* leakage and reduction method at 300-ml bladder volume

	Preop leakage during reduction testing	Postoperative SUI		Sensitivity	Specificity	PPV	NPV
		N	%	%	%	%	%
All methods	Leakage	31/52	60	24	88	60	61
	No leakage	96/245	39				
Pessary	Leakage	1/2	50	5	96	50	59
	No leakage	19/46	41				
Manual	Leakage	4/8	50	18	90	50	66
	No leakage	18/53	34				
Swab	Leakage	11/14	79	33	93	79	65
	No leakage	22/63	35				
Forceps	Leakage	4/8	50	17	84	50	51
	No leakage	20/41	49				
Speculum	Leakage	11/20	55	39	74	55	60
	No leakage	17/42	40				

Table 4

Postoperative rates of stress urinary incontinence in *Burch* group by leakage and reduction method at 300-ml bladder volume

	Preoperative leakage during reduction testing	Postoperative	SUI	Sensitivity	Specificity	PPV	NPV
		N[a]	%	%	%	%	%
All methods	Leakage	22/60	37	33	83	37	80
	No leakage	45/227	20				
Pessary	Leakage	1/3	33	11	94	33	78
	No leakage	8/37	22				
Manual	Leakage	5/11	45	28	86	45	74
	No leakage	13/50	26				
Swab	Leakage	5/18	28	29	80	28	81
	No leakage	12/63	19				
Forceps	Leakage	3/13	23	38	76	23	86
	No leakage	5/36	14				
Speculum	Leakage	8/15	53	53	83	53	83
	No leakage	7/41	17				

PPV Positive predictive value, *NPV* negative predictive value

[a]There were two attempts at prolapse reduction stress testing per subject.

Table 5

Postoperative rates of stress incontinence by study group and by various methods of prolapse reduction at 300 ml

Prolapse reduction		Control		Burch	
		N	% Incontinent 300 ml	N	% Incontinent 300 ml
Either of two methods	No leakage	41/109	38	22/106	21
	Leakage	23/40	58	12/38	32

Table 6

Postoperative rates of stress incontinence by study group and by various methods of prolapse reduction at maximum capacity

Prolapse reduction		Control		Burch	
		N	% Incontinent Maximum capacity[a]	N	% Incontinent Maximum capacity[a]
Second method	No leakage	31/80	39	12/71	17
	Leakage	20/39	51	14/38	37

[a]Testing at maximum capacity was performed with second reduction method only.

Table 7

Leak point pressures for Burch and control (no Burch) group

Volume		Burch						Control (no Burch)					
		Continent			Incontinent			Continent			Incontinent		
		N	Mean	Standard error	*N*	Mean	Standard error	*N*	Mean	Standard error	*N*	Mean	Standard error
300 ml	CLPP	29	78.69	7.64	19	79.11	10.17	16	104.56	11.24	27	91.44	6.78
	VLPP	22	48.41	4.47	17	67.47	8.36	11	37.09	7.05	22	52.96	5.47
Maximum capacity	CLPP	20	83.80	11.06	12	103.25	11.84	15	105.07*	8.98	17	77.12*	7.80
	VLPP	15	59.80	6.08	11	68.55	12.63	13	63.31	9.71	16	44.13	6.81

CLPP Cough leak point pressure, *VLPP* Valsalva leak point pressure

* $p<.05$