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Predicting the Outcome of Mid-urethral Tape Surgery for Stress Urinary Incontinence Using Preoperative Urodynamics – A Systematic Review

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Rezumat

Valoarea predictivă a investigațiilor urodinamice preoperatorii în evaluarea rezultatelor terapiei chirurgicale a incontinenței urinare de efort cu bandelete suburetrale. Revedere sistematică a literaturii

Evaluarea urodinamică este frecvent utilizată în serviciile de uroginecologie, în special în scop diagnostic de rutină preoperator sau pentru cazurile complexe. Parametrii urodinamici, în special presiunea de pierdere urinară la Valsalva (VLPP) și presiunea uretrală maximă (MUCP), sunt evaluați pentru valoarea lor predictivă pentru succesul/eșecul chirurgiei incontinenței urinare de efort (IUE). În ciuda argumentelor în creștere, rolul lor predictiv asociat chirurgiei IUE este discutabil. Studiul nostru revizuie în mod sistematic literatura de specialitate publicată între ianuarie 1990 și ianuarie 2014, analizând valoarea predictivă a parametrilor urodinamici pentru anticiparea prognosticului postoperator. S-a calculat riscul relativ de eșec al tratamentului chirurgical al IUE cu bandeleta suburetrală la pacienții cu MUCP și VLPP reduse comparativ cu cei cu parametri urodinamici în limite normale. MUCP preoperator scăzut s-a asociat cu un risc mai mare de eșec pentru ambele tehnici, transobturatorie și retropubică (RR 1.83; 95% interval de confidență (CI) 1.44-2.33 și respectiv RR 1.41; 95% CI 1.17-1.69). VLPP preoperator scăzut a fost de asemenea predictiv pentru risc crescut de eșec pentru ambele abordări, transobturatorie și retropubică (RR 1.76; 95% CI 1.37-2.28 și respectiv RR 2.01; 95% CI 1.56-2.60). În concluzie, MUCP și VLPP preoperatorii ar putea fi utilizate ca factori predictivi pentru prognosticul postoperator după chirurgia cu bandeleta suburetrală pentru IUE.

Cuvinte cheie: incontinența urinară, VLPP, MUCP, bandeleta suburetrală

Abstract

Urodynamics are currently widely used in most of urogynecology services, mainly as a diagnostic tool routinely preoperatively or for complicated cases. The urodynamic parameters, mainly Valsalva leak point pressure (VLPP) and maximum urethral closure pressure (MUCP), are increasingly researched for the promising value in predicting the outcome of urinary incontinence surgery. Despite the increasing evidence, their predictive role for mid-urethral sling surgery outcome is still unclear. We systematically searched the literature for articles published between January 1990 to January 2014, analysing the value of urodynamic variables in predicting the outcome of mid-urethral sling surgery. We calculated relative risks of failure of surgery for patients with low MUCP and VLPP compared with those with high values. Low preoperative MUCP was associated with higher risk of failure for both transobturator and retropubic techniques (RR 1.83; 95% confidence interval (CI) 1.44-2.33 and RR 1.41; 95% CI 1.17-1.69 respectively). Low preoperative VLPP was predictive as well for higher risk of failure for both transobturator and retropubic routes (RR 1.76; 95% CI 1.37-2.28 and RR 2.01; 95% CI 1.56-2.60 respectively). Concluding, preoperative MUCP and VLPP could be used as predictors for postoperative outcome after mid-urethral sling surgery for SUI.

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Key words: urinary incontinence, Valsalva leak point pressure, maximum urethral closure pressure, mid-urethral tape

Introduction

The prevalence of stress urinary incontinence is high in the general population. It varies widely between 5% and 69% in the general population; the estimated prevalence of daily incontinence in middle aged and older patients was found to be in the range of 5-15% (1). Stress urinary incontinence (SUI) occurred in 4.7% of nulliparous women, 6.9% of patients delivered by cesarean section and 12.2% of patients with history of vaginal deliveries (2). The proportion of different types of urinary incontinence is approximated at 50% for SUI, 36% for mixed urinary incontinence (MUI) and 14% for urge urinary incontinence (UUI) (3). The burden of urinary incontinence treatment on the health system in UK was approximated at £233m annually and of billion dollars in US (4,5).

When conservative measures fail, SUI is usually managed surgically. The widespread use of minimally invasive surgery for SUI, especially mid-urethral tapes, has consistently increased the rate of surgical treatment of urinary incontinence in women. Although sling surgery is very effective in curing SUI, failure of therapy brings significant lower success rate for subsequent similar surgery. Therefore, predicting the outcome of surgery with mid-urethral tapes is important for the appropriate counselling of the patient about to undergo surgery. The treatment of SUI aims an improvement of the patient's quality of life; hence, one of the most important issues of the therapy is to meet the patient's expectations.

The anticipation of success or failure of therapy can be achieved by identifying and analysing the presence of associated risk factors. It is not an easy task considering the abundance of conflicting evidence on this subject. Many researches guided their attention towards preoperative urodynamics in an effort to find a reliable tool that can predict success or failure of therapy. Urodynamics, defined by the International Continence Society (ICS), represents the study of the function and dysfunction of the urinary tract by an appropriate method (6).

Urodynamic testing evaluates the function of the lower urinary tract by catheterization (invasive tests) or non-invasively. The non-invasive tests are frequency/volume charts, urinalysis and mid-stream urine culture, ultrasound measurement of residual urine volume, urine flowmetry (7). The most common invasive test is the multi-channel cystometry that evaluates the relationship between pressure and volume during bladder filling and emptying (8). Ambulatory bladder pressure assessment and videocystometry are less frequently used invasive options.

Many studies challenged the role of invasive urodynamics in the evaluation of patients with urinary incontinence. Urodynamics is widely used nowadays before continence surgery, particularly in the presence of mixed symptoms or after previously failed continence procedures. Although the role of urodynamics in the preoperative evaluation of patient with SUI symptoms was questioned by the National Institute for Health and Clinical Excellence (NICE) in 2006 (9), most of the urogynecologists and urologists in UK are however using mandatory urodynamic testing before surgery for SUI (10). NICE guidelines mention that cystometry testing is not recommended before conservative management of SUI and there is no evidence to use it for patients with obvious clinical diagnosis of SUI (9). The same guidelines recommend preoperative urodynamic testing before surgery for SUI when there are symptoms of detrusor overactivity or voiding dysfunction or after previous failed continence surgery (9).

Preoperative urodynamic testing is thus debatable. Although it is invasive, time and resource consuming (11), it might bring invaluable insights in the pathophysiology of urinary incontinence and help identify the cases more prone to fail after surgical treatment. Although mid-urethral tapes are very effective in treating SUI, there are still about 20% of the patients who have undergone this type of surgery and will fail, experiencing persistent SUI postoperatively (12). Increasing severity of UI adversely impacts surgical outcome. Intrinsic sphincter deficiency (ISD) is associated usually with severe urinary incontinence. ISD is diagnosed using urodynamics in patients with maximum urethral closure pressure (MUCP) under 20 cm H2O on urethral pressure profilometry or Valsalva leak point pressure (VLPP) under 60 cm H2O. The failure of surgical treatment occurs more commonly in patients with severe SUI. Most frequently, the maximum urethral closure pressure (MUCP) and Valsalva leak point pressure (VLPP) are the urodynamic parameters used to grade SUI severity.

Our objective was to systematically review the existing literature regarding the capacity of preoperative urodynamic evaluation, namely MUCP and VLPP parameters, to predict postoperative outcome after surgical treatment of SUI with mid-urethral tapes.

Material and Method

Search strategy

A comprehensive search of the literature was undertaken to identify the original research paper published between January 1990 and January 2014. The following online resources were searched: PubMed/Medline, Cochrane Library, Embase, Web of Knowledge and Clinical Trials.gov, using the following keywords: urodynamics, urinary incontinence, cystometry, cystometrogram, pressure flow, urethral pressure profile, uroflowmetry, maximum urethral closure pressure, leak point pressure, stress urinary incontinence, mid-urethral tape, sling. Medical Subject Headings (MeSH) terms were used as well, namely "urinary incontinence" and "urodynamics". Unpublished communications from recent meetings of relevant profile associations (International Urogynecology Association, International Continence Society, American Urogynecological Society and Society for Urodynamics,

Female Pelvic Medicine and Urogenital Reconstruction) were also reviewed. Relevant articles from the references of review articles on the studied theme were extracted and assessed.

Study selection

Inclusion criteria for the present review were: original papers reporting outcomes of midurethral tape surgery; numeric values of preoperative urodynamic parameters; outcomes reported separately for different techniques (transobturator or retropubic), related to preoperative urodynamic parameters. We excluded studies reporting on procedures other than synthetic midurethral tapes (Burch colposuspension, pubovaginal fascial slings etc), with less than 30 patients or not reporting on MUCP or VLPP variables.

Outcomes and data analysis

The selected studies for analysis were graded on levels of strength and quality of evidence using the Grades of Recommendation Assessment, Development and Evaluation system (GRADE) (13). The studies included were stratified on three grading levels: A – randomized controlled trials, B – observational studies with good methodology and C – case series or observational studies with clear evidence of major bias.

The urodynamic parameters evaluated were maximum urethral closure pressure (MUCP) and Valsalva leak point pressure (VLPP), urodynamic parameters that look most promising for prediction of success/failure of midurethral tape surgery. Papers assessing patients with low urodynamic parameters versus those with high urodynamic values regarding success or failure of midurethral tape therapy were taken into account. The outcomes of surgery were stratified as success or failure; depending on the method of assessment, we considered objective, subjective and composite success rate. Objective success rate was considered if the outcome was evaluated with clinical examination, cough test, pad test, urodynamics or validated questionnaires. Subjective success rate was assessed considering patient's complaints or symptom description. When the treatment outcome was evaluated using both types already mentioned, the outcome was considered composite. The present review assessed the studies that reported data on comparative outcomes for low versus high urodynamic parameters groups. We calculated relative risk of failure for low versus high UDS parameters groups and 95% confidence intervals using EpiInfo software. P value was considered statistically significant for values less than 0.05.

Results

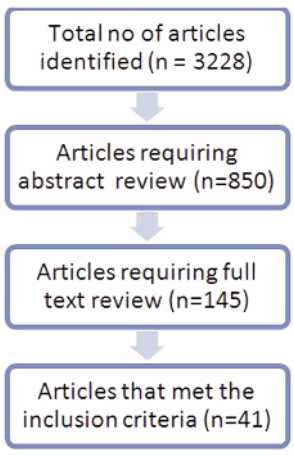
The literature database search revealed 3,228 articles of which 850 articles were selected for abstract review. After abstract review, we selected 145 articles for full text review. The inclusion criteria were met by 41 studies that were evaluated quantitatively and qualitatively in our synthesis. Randomized controlled studies and observational studies, prospective or retrospective, were analysed; most of them were observational studies. The outcomes were stratified on categories depending on the assessment method and were divided in subjective, objective and composite (*Table 1, 2*). We calculated the relative risk (RR) of the outcomes and the 95% confidence intervals (CI). We assessed the risk of failure of therapy for the patients with low values at UDS evaluation compared with high values group. Consequently, we calculated the RR for failure of therapy (mid-urethral sling surgery) in the exposed group (low UDS values) compared to the non-exposed group (high UDS values). RR of outcome (failure of therapy) is the probability of failure of surgery in the exposed group (low UDS parameters). If RR >1, failure of sling surgery was more likely to occur in the exposed group, while for RR <1, failure is less likely to occur in the exposure group. If RR $=1$, there is no difference regarding the outcome between low and high UDS parameters groups.

Most of the studies reported outcomes as composite or objective and less frequent as subjective. We assessed the data separately depending on the route used, transobturator (TO) or retropubic (RP), according to the increasing evidence of different outcomes of the two techniques in selected populations (12,14).

The cutoff between low and high UDS values varied considerably between analysed studies, rendering the review process difficult; cutoff value for VLPP was considered in most studies to be 60 cm H2O, while the threshold for MUCP was 20, 40 or sometimes even 60 cm H2O. Other studies did not mention any threshold values, defining the groups only as having or not intrinsic sphincter deficiency (ISD); they could not be included in our analysis.

The selected studies are listed separately for transobturator (*Table 1*) and retropubic route (*Table 2*).

Quantitative assessment of relative risk (RR) for studies evaluating the outcome after TO tape in groups with SUI and high VLPP (generally over 60 cmH2O) versus low VLPP is presented in *Fig 1*. The pooled RR resulting from 10 selected studies was 1.76 (95% CI 1.37-2.28), indicating greater risk of failure of TO tape surgery in the low VLPP group. When the patients treated with RP tape were



Search flow-chart

Table 1. *Studies assessing the predictive value of VLPP/MUCP in patients after transobturator tape for SUI (FU – follow-up, UDS – urodynamic, A/VLPP – Abdominal/Valsalva leak point pressure, MUCP – maximum urethral closure pressure, TOT – transobturator tape, RPT – retropubic tape)*

Author/ Year	Design	No patients	Outcome	Quality	FU time (months)	UDS parameter	Predictive/ Not
Delorme 2004 [15]	Observational prospective	150	Composite	C	17	MUCP	High MUCP predicts cure
Roumeguere 2005 [16]	Observational retrospective	120	Objective	C	12	MUCP	High MUCP (>30) predictive cure
Romancik 2006 [17]	Observational retrospective	65	Objective	C	12	VLPP	High VLPP predicts success obj, but no difference for subj
OConnor 2006 [18]	Observational prospective	43	Subjective	C	6	VLPP	Low VLPP predictive for failure
Miller 2006 [19]	Observational retrospective	145	Objective	C	3	MUCP	Low MUCP predictive for failure
Porena 2007 [20]	RCT	148	Composite	A	31	VLPP, MUCP	Not predictive for composite
Chen 2007 [21]	Observational prospective	54	Objective	C	9	MUCP	MUCP not predictive
Guerette 2008 [22]	Observational prospective	70	Composite	C	8.1	VLPP, MUCP	High VLPP (>60) and MUCP (>40) predictive for success
Poza 2008 [23]	Observational prospective	254	Composite	B	12 (251 pts) 24 (62 pts)	MUCP	High MUCP predictive for success
Anast 2008 [24]	Observational retrospective	151	Composite	B	14	VLPP	VLPP not predictive
Constantini 2008 [25]	RCT	145	Objective	A	32 for RPT 31 for TOT	VLPP	VLPP not predictive for RPT/TOT
Araco 2008 [26]	RCT	208	Composite	A	12	ALPP	Low ALPP (<60) predictive for failure for TOT, but not RPT
Hsiao 2009 [27]	Observational retrospective	121	Composite	C	25	MUCP	Low MUCP<40 predictive for failure of TOT
Houwert 2009 [28]	Observational retrospective	387	Subjective	B	12	MUCP	Low MUCP for TOT only is predictive for failure
Abdel Fattah 2009 [29]	RCT	341	Objective	A	6	MUCP	Low MUCP predictive for failure (previous incontinence surgery as well)
Karateke 2009 [30]	RCT	164	Objective	A	12	VLPP	VLPP not predictive
Rechberger 2009 [31]	RCT	398	Objective	A	18	VLPP	High VLPP predictive for success of TOT, but not for RPT
Romancik 2010 [32]	Observational prospective	97	Objective, subjective	C	6	VLPP	Low VLPP predictive of failure
Abdel Fattah 2012 [33]	RCT	341	Objective	A	36	MUCP	MUCP not predictive

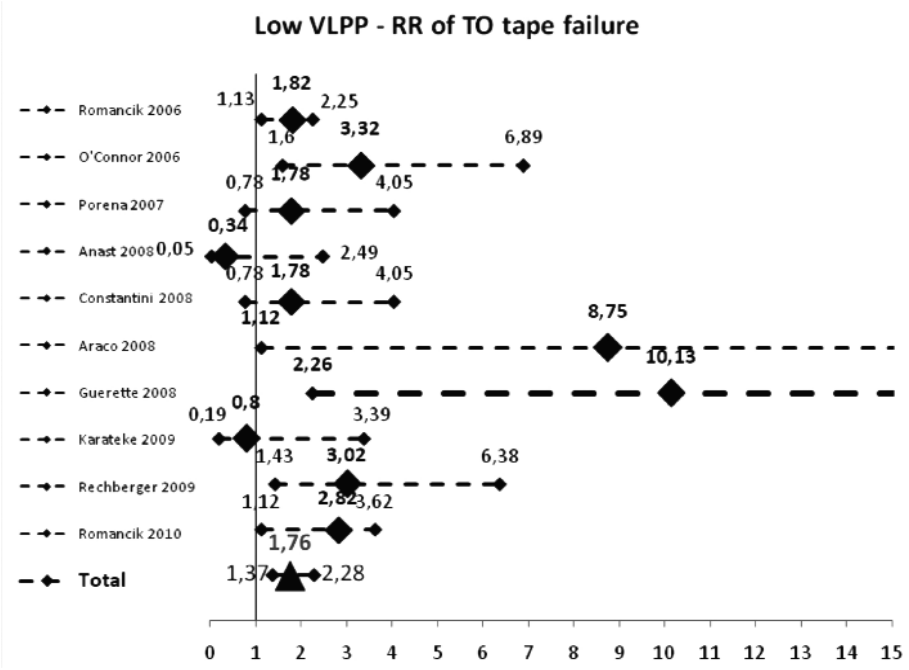


Figure 1. *Relative risk of TO tape failure in patients with SUI and low VLPP*

Table 2. *Studies assessing the predictive value of VLPP/MUCP in patients after retropubic mid-urethral tape for SUI (FU – follow-up, UDS – urodynamic, A/VLPP – Abdominal/Valsalva leak point pressure, MUCP – maximum urethral closure pressure, TOT – transobturator tape, RPT – retropubic tape)*

Author/ Year	Design	No patients	Outcome	Quality	FU time (months)	UDS parameter	Predictive value
Lebret 2001 [34]	Observational prospective	100	Composite	C	14	MUCP	Low MUCP predictive for failure
Soulie 2001 [35]	Observational prospective	52	Subjective	C	15.2	MUCP	MUCP not predictive
Fritel 2002 [36]	Observational retrospective	78	Objective	C	9	MUCP	MUCP not predictive
Sevestre 2003 [37]	Observational retrospective	76	Subjective	C	24.6	MUCP	MUCP not predictive
Paick 2004 [38]	Observational prospective	60	Composite	B	35	VLPP, MUCP	VLPP, MUCP not predictive
Paick 2004 [39]	Observational prospective	221	Composite	B	10.5	VLPP, MUCP	Low VLPP and MUCP predictive for failure
Liapis 2004 [40]	Observational prospective	37	Composite	C	26	MUCP	Low MUCP predictive for failure
Doo 2006 [41]	Observational prospective	134	Composite	B	60	VLPP	Low VLPP predictive for failure
Viereck 2006 [42]	Observational prospective	191	Composite	B	34.6	MUCP	Low MUCP predictive for failure
Miller 2006 [19]	Observational retrospective	145	Objective	C	3	MUCP	Low MUCP predictive for failure
Kuuva 2006 [43]	Observational prospective	129	Composite	C	72	MUCP	MUCP not predictive
Koops 2006 [44]	Observational prospective	809	Objective	C	24	MUCP	MUCP not predictive
Bai 2007 [45]	Observational retrospective	111	Composite	C	12	VLPP, MUCP	MUCP, VLPP not predictive
Clemons 2007 [46]	Observational prospective	36	Composite	C	20.9	MUCP	Low MUCP predictive for failure
Porena 2007 [20]	RCT	148	Composite	A	31	VLPP, MUCP	VLPP, MUCP not predictive
Chene 2007 [47]	Observational prospective	82	Composite	C	60	MUCP	MUCP not predictive
Meschia 2007 [48]	Observational retrospective	325	Objective, subjective	C	32	MUCP	MUCP not predictive
Lee 2008 [49]	Observational retrospective	138	Composite	C	67.2	ALPP	Low VLPP and MUCP predictive of failure
Araco 2008 [26]	RCT	208	Composite	A	12	ALPP	Low ALPP (<60) predictive for failure of TOT, but not of TVT
Constantini 2008 [25]	RCT	145	Objective	A	32 for RPT 31 for TOT	VLPP	VLPP not predictive for RPT/TOT
Noblett 2008 [50]	Observational prospective	118	Composite	C	12	MUCP	Low MUCP predictive of failure
Liapis 2009 [51]	Observational prospective	31	Composite	C	18.6	MUCP	Reduced statistical significance; uninterpretable Low MUCP (<20) predictive for failure
Karateke 2009 [30]	RCT	164	Objective	A	12	VLPP	VLPP not predictive
Rechberger 2009 [31]	RCT	398	Objective	A	18	VLPP	Low VLPP predictive for failure of TOT, but not for RPT
Choo 2012 [52]	Observational retrospective	136	Subjective	C	49.7	VLPP	Low VLPP predictive for failure
Hwang 2012 [53]	Observational retrospective	175	Composite	C	32	VLPP	Low VLPP predictive of failure
Jun 2012 [54]	Observational retrospective	136	Subjective	C	50	MUCP, VLPP	VLPP, MUCP not predictive for failure
Han 2012 [55]	Observational prospective	96	Objective	C	36	VLPP, MUCP	Low MUCP not predictive, low VLPP predictive of failure of RPT

similarly assessed (15 studies), a RR of 2.01 (95% CI 1.56-2.60) was found (*Fig. 3*), revealing a statistically significant greater risk of failure of surgery in patients with low VLPP. When the outcome of sling surgery was assessed considering low maximum urethral closure pressure (MUCP) as predictor of failure, a RR of 1.83 (95% CI 1.44-2.33) was found for TO tape (*Fig. 2*) and 1.41 (95% CI 1.17-1.69) for RP tape (*Fig. 4*), both statistically significant. Preoperative low MUCP and VLPP were predictive for failure of mid-urethral sling surgery, independent of the route used.

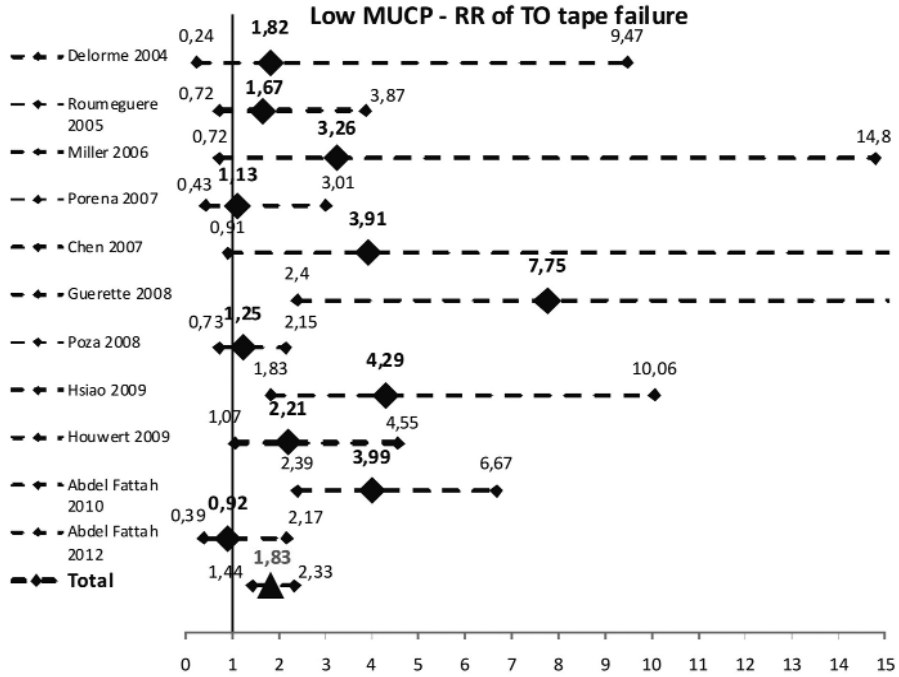


Figure 2. *Relative risk of TO tape failure in patients with SUI and low MUCP*

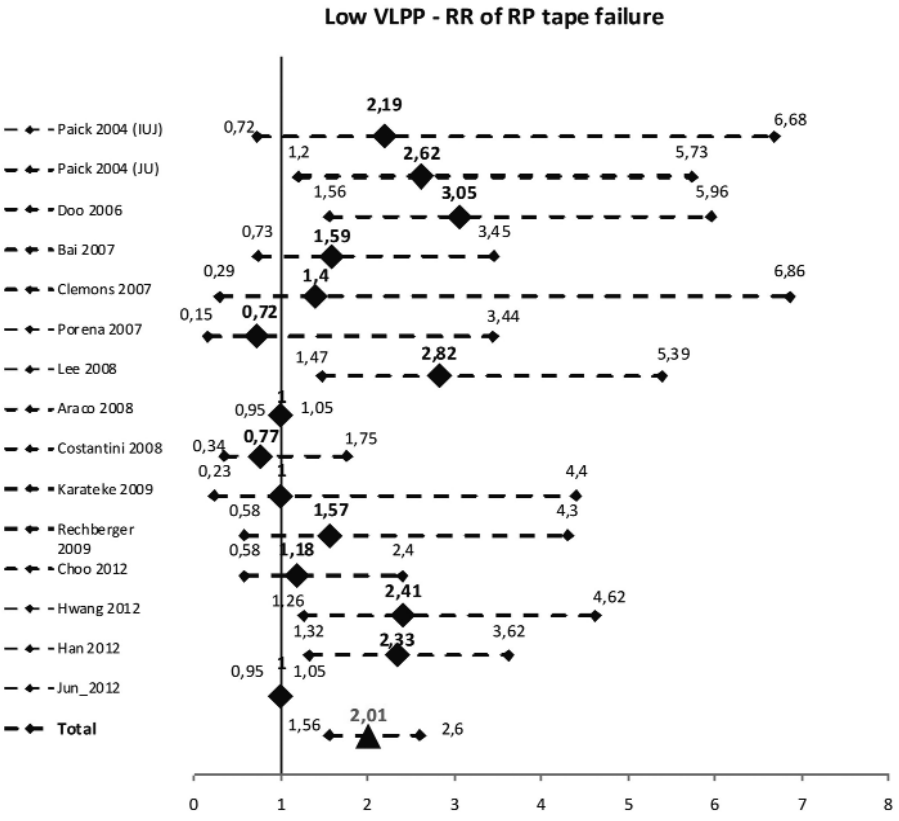


Figure 3. *Relative risk of RP tape failure in patients with SUI and low VLPP*

Discussion

Urodynamic investigations are being widely used in urogynecology, most of the urogynecologic services having it at hand; however, there is at present no clearly defined consensus on the pre-therapeutic use of urodynamics. It seems reasonable to perform UDS investigations in patients with mixed symptoms, failed previous surgery or with discordant symptoms compared with the objective findings.

A recent review evaluated the predictive value of UDS

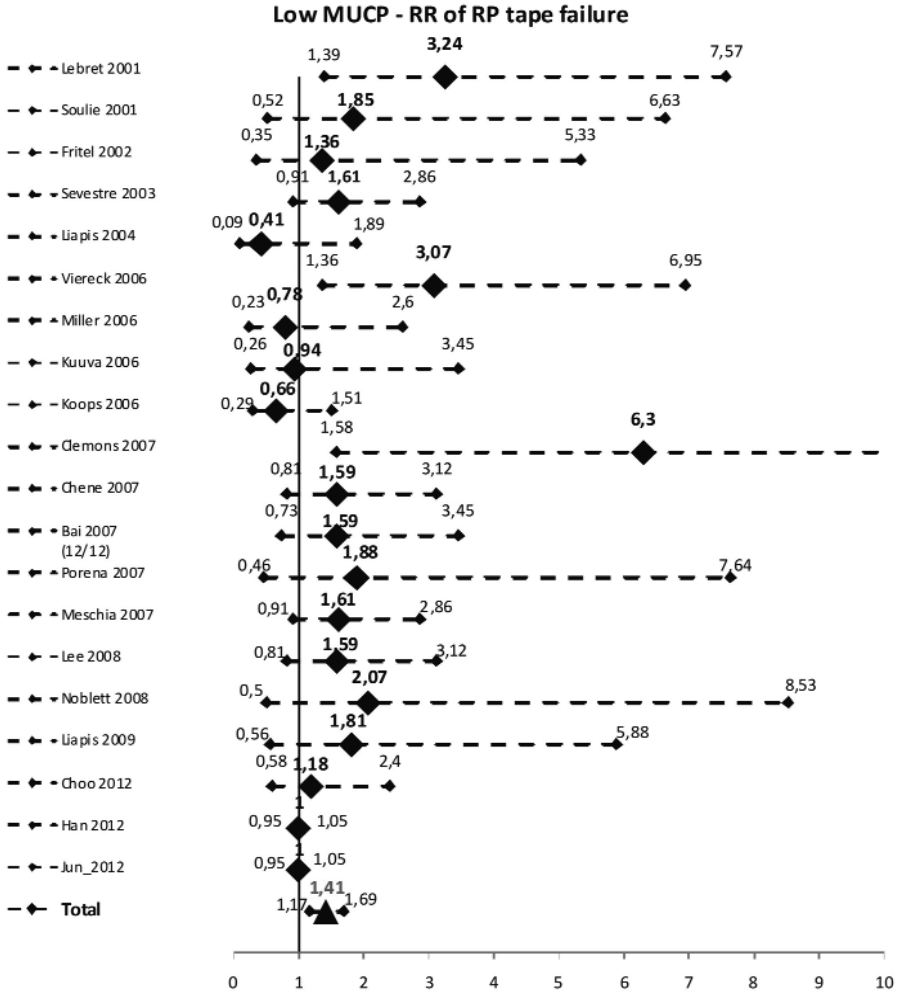


Figure 4. *Relative risk of RP tape failure in patients with SUI and low MUCP*

parameters regarding the outcome of mid-urethral sling surgery. Subjective, objective and composite outcomes were analysed separately for transobturator and retropubic routes. Increased rates of success were generally found for both types of approaches and for different outcomes in patients with higher preoperative UDS parameters, namely MUCP and VLPP. More data regarding the cutoff values of UDS parameters are still needed though (56).

Although we found good evidence in the literature supporting the role of preoperative urodynamics for predicting surgery outcome, there are still a couple of issues that should be discussed. First of all, cutoff values for urodynamic parameters varied between studies. If sometimes low MUCP meant values below 20 cm H2O, in other studies the cutoff value was 40 or even 60 cm H2O; for VLPP, most authors used as threshold 60 cm H2O. Anyway, finding the right cutoff urodynamic parameter was beyond the scope of our review. The second problem we encountered was a variable follow-up interval; if a parameter does not predict the outcome at a given follow-up interval, it might be predictive later in time at subsequent follow-ups. For example, a study found lower cure rates of RP tapes in ISD group at 1 month follow-up, but no differences between groups at 3, 6 or 12 months follow-up assessment (45). An interval of follow-up time after which UDS parameters are predictive remains to be established.

Part of the analysed studies included small number of participants and might not have been appropriately powered to identify the differences between groups regarding urodynamic parameters or cure/failure rates. Paick published two studies in 2004 with discordant conclusions, illustrating the importance of methodology regarding the association of urodynamic parameters with surgical outcome. The first study with limited number of patients (namely 60), but with longer follow-up (minimum 2 years), failed to identify any association between VLPP and RP tape outcome (38), while the second study, comprising of 221 patients with a mean follow-up of 10.5 months, found significantly lower cure rates of RP tape in patients with VLPP less than 60 cm H2O (39).

Another limitation of the present review is the fact that the summarized studies had most of the times other primary objectives than assessing the predictive value of UDS parameters. They were not designed specifically to determine the predictive value of UDS variables that came only as secondary findings.

The strength of our study is given by the extensive systematic search of the literature, with clear methodology, following the steps proposed by PRISMA algorithm (57); the

selected studies were graded upon the quality of evidence and strength of recommendation (58).

The finding of predictive UDS parameters is one step forward in clarifying the role of urodynamics in tailoring the therapy for urinary incontinence. There are though still many questions to be answered – what is the UDS threshold value to separate between low and high risk of failure of mid-urethral sling therapy? Is it the same value for both routes? Is there a single parameter enough to predict the success or failure of therapy? How is this going to change the practice regarding preoperative UDS practice and choice of therapy?

Even though there appear to be groups of patients at risk of failure of mid-urethral sling surgery depending on their preoperative urodynamic parameters, it will be probably hard to substitute the surgical approach with mid-urethral slings that have proved to be until now highly successful and convenient for patients with SUI. However, finding new reliable parameters that will optimize our predictive capacity regarding postoperative results, could improve the value of preoperative counselling so that surgical treatment will better meet patients' expectations.

Conclusions

Low preoperative VLPP and MUCP correlate with higher risk of failure of surgical treatment for SUI with mid-urethral slings, with risk increase of between 1.5 and 2 times in patients with low preoperative values, for both types of routes (transobturator and retropubic). There is no consensus to date regarding particular thresholds for UDS variables that could be correlated with increased risk of success or failure of surgery for SUI. Cutoff values for UDS parameters are still to be determined and their impact on clinical practice remains to be better defined in an effort to optimize urinary incontinence therapy.

Disclosure

The authors report no conflict of interest.

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