

## **Diagnosis and management of adult female stress urinary incontinence: guidelines for clinical practice from the French College of Gynaecologists and Obstetricians.**

Xavier Fritel, Arnaud Fauconnier, Georges Bader, Michel Cosson, Philippe Debodinance, Xavier Deffieux, Pierre Denys, Philippe Dompeyre, Daniel Faltin, Brigitte Fatton, et al.

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Title:

Diagnosis and management of adult female stress urinary incontinence.

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Authors:

Xavier Fritel, Arnaud Fauconnier, Georges Bader, Michel Cosson, Philippe Debodinance, Xavier Deffieux, Pierre Denys, Philippe Dompeyre, Daniel Faltin, Brigitte Fattou, François Haab, Jean-François Hermieux, Jacques Kerdraon, Pierre Mares, Georges Mellier, Nathalie Michel-Laaengh, Cédric Nadeau, Gilberte Robain, Renaud de Tayrac, and Bernard Jacquetin.

Correspondence

Dr Xavier FRITEL

Service de Gynécologie et Obstétrique, CHU Jean Bernard, F-86021 POITIERS CEDEX,  
France

Tel +335 49 44 39 45

Fax +335 49 44 39 10

[fritel.xavier@orange.fr](mailto:fritel.xavier@orange.fr)

## Condensation

The guidelines address for female stress incontinence, diagnosis, conservative and surgical treatment, surgery complications, and association with pregnancy, postpartum, old age, and pelvic organ prolapse.

## Abstract

Diagnosis and management of adult female stress urinary incontinence.

Guidelines for clinical practice from the French College of Gynaecologists and Obstetricians.

X. Fritel, A. Fauconnier, G. Bader, M. Cosson, P. Debodinance, X. Deffieux, P. Denys, P. Dompeyre, D. Faltin, B. Fatton, F. Haab, J.-F. Hermieux, J. Kerdraon, P. Mares, G. Mellier, N. Michel-Laaengh, C. Nadeau, G. Robain, R. de Tayrac, and B. Jacquetin.

Urinary incontinence is a frequent affliction in women and may be disabling and costly {LE1}. When consulting for urinary incontinence, it is recommended that circumstances, frequency and severity of leaks be specified {Grade B}. The cough test is recommended prior to surgery {Grade C}. Urodynamic investigations are not needed before lower urinary tract rehabilitation {Grade B}. A complete urodynamic investigation is recommended prior to surgery for urinary incontinence {Grade C}. In case of pure stress urinary incontinence, urodynamic investigations are not essential prior to surgery provided the clinical assessment is fully comprehensive (standardised questionnaire, cough test, bladder diary, postvoid residual volume) with concordant results {PC}. It is recommended to start treatment for stress incontinence with pelvic floor muscle training {Grade C}. Bladder training is recommended at first intention in cases with overactive bladder syndrome {Grade C}. For overweight patients, loss of weight improves stress incontinence {LE1}. For surgery, sub-urethral tape (retropubic or transobturator route) is the first line recommended technique {Grade B}. Sub-urethral tape surgery involves intraoperative risks, postoperative risks and a risk of failure which must be the subject of prior information {Grade A}. Elective caesarean section and systematic episiotomy are not recommended methods of prevention for urinary incontinence {Grade B}. Pelvic floor muscle training is the treatment of first intention for pre- and postnatal urinary incontinence {Grade A}. Prior to any treatment for an elderly woman, it is recommended to screen for urinary infection using a test strip, ask for a bladder diary and measure postvoid residual volume {Grade C}. It is recommended to carry out a cough test and look for occult incontinence prior to surgery for pelvic organ prolapse {Grade C}. It is recommended to carry out urodynamic investigations prior to pelvic organ prolapse surgery when there are urinary symptoms or occult urinary incontinence {Grade C}.

## Key-words:

stress urinary incontinence, pelvic organ prolapse, urodynamic investigation, pelvic floor muscle training, sub-urethral tape.

## ***Introduction***

The rapid development of medical techniques and abundance of scientific publications makes it difficult for the clinician to assimilate everything and draw conclusions. For example, during the year 2009, 274 articles about stress urinary incontinence surgery in female were published and referenced in PubMed. One of the consequences is the risk of considerable variations in practices, some of which may be unnecessary or even inappropriate.

Female urinary stress incontinence is a frequent, disabling and costly pathology. Over the past 10 years surgical treatment for this condition has been transformed by the advent of sub-urethral sling surgical technique. Recommendations on the subject have already been drawn up by several scientific societies or institutions, such as the International Consultation on Incontinence, International Continence Society, International Urogynecological Association, American College of Obstetricians and Gynecologists, Society of Obstetricians and Gynaecologists of Canada, European Urologic Association, French Urological Association, National Institute for Clinical Excellence, or National Institute of Health. The intention of the French College of Gynaecologists and Obstetricians (CNGOF) is that our approach should be complementary to these previous undertakings. To this end we have chosen the approach based on guidelines for good clinical practice defined by the French High Authority for Health (HAS - Haute Autorité de Santé)<sup>1</sup> and limited our subject to adult females without any neurological pathology and, where possible, to stress urinary incontinence.

## ***Method***

The sponsor (French College of Gynaecologists and Obstetricians - CNGOF) appointed a multidisciplinary organisation committee tasked with defining the exact questions to be put to the expert authors, to choose these experts, follow them up and draft the synthesis of recommendations resulting from their work. The questions concerned risk factors and consequences of female urinary incontinence, its diagnosis and clinical assessment, urodynamic investigations, conservative treatment, surgical treatment, complications of sub-urethral tape surgery, urinary incontinence during pregnancy and the postpartum period, in elderly women, and the association of pelvic organ prolapse and urinary incontinence. The experts analysed the scientific literature on the subject in order to answer the questions raised. For each question, each overview of validated scientific data was associated with a level of evidence established according to the quality of available data, using the working framework defined by the HAS (LE1: Very powerful randomised comparative trials, meta-analysis of

randomised comparative trials; LE2: Not very powerful randomised trials, well-run non randomised comparative studies, cohort studies; LE3: case-control studies; LE4: non-randomised comparative studies with large biases, retrospective studies, transversal studies, series of cases). Concerning questions of prevalence, diagnosis and prognosis, the levels of evidence were set according to the working framework proposed by the University of Oxford Centre for Evidence Based Medicine ([www.cebm.net](http://www.cebm.net)). The synthesis of recommendations was drafted by the organising committee based on the replies given by the expert authors. Each recommendation for practice was allocated a grade which not only depends on the level of evidence, but also on the feasibility and ethical factors. Grade A represents the scientifically established evidence; grade B represents a scientific presumption; grade C is based on a low level of evidence, generally founded on LE3 or LE4. In the absence of any conclusive scientific evidence, some practices have nevertheless been recommended on the basis of agreement between all the members of the working group (professional consensus, PC). Cases of professional consensus have been kept to the strict minimum.

All the texts along with the synthesis of recommendations were reviewed by persons not involved in the work, i.e. practitioners in the various specialities concerned and working in varying situations (public, private, university, or non-university establishments). Once reviewing had been completed, changes were made. The methods, texts by the expert authors, synthesis of recommendations together with the introduction by the President, Bernard Jacquetin, have already been published in French in a special number of the CNGOF journal.<sup>2-13</sup>

### ***Synthesis of recommendations***

The term urinary incontinence describes the complaint of involuntary loss of urine. Urinary incontinence is a frequent affliction in adult women and may be disabling and costly {LE1}. The main types are stress urinary incontinence, urge incontinence, and mixed incontinence. Stress urinary incontinence describes loss of urine during exertion, coughing or sneezing. Urge incontinence is involuntary loss of urine preceded or accompanied by a strong desire to pass urine. Mixed urinary incontinence is the association in variable proportions of stress and urge incontinence. There is not always a correspondence between urinary symptoms and physical/pathological mechanisms.

## **1 Assessment of female urinary incontinence**

### **1.1 Clinical assessment of female urinary incontinence**

The severity of urinary incontinence can be assessed by various methods such as a urinary symptoms questionnaire, frequency/volume chart (bladder diary), quality of life questionnaire, or pad-test {LE2}. A 3-days bladder diary provides the means for assessing voiding frequency and volume together with the frequency of leaks {LE2}.

In a patient consulting for urinary incontinence, it is recommended that the circumstances, frequency and severity of leaks of urine be specified {Grade B}. There are questionnaires in French to assess the circumstances of leaks, severity and impact of urinary incontinence. In case of overactive bladder syndrome (urgency, frequency, nocturia, or urge incontinence,) it is recommended to use a bladder diary {Grade C}.

The cough test provides the means for documenting stress urinary incontinence. This clinical test is simple and reproducible {LE4}. A positive cough test carried out with an empty bladder, patient in supine position, tends to indicate an intrinsic urethral sphincter deficiency {LE4}.

The cough test is recommended for documenting stress urinary incontinence prior to surgery {Grade C}. In case of a negative cough test, it is recommended to check the bladder volume and repeat the test, in particular with the patient standing upright {Grade C}.

Clinical methods proposed for assessing urethral mobility are observation, measurement of POPQ point Aa, support manoeuvres and the Q-tip test. Support manoeuvres (sub-urethral and sub-cervical) have not been sufficiently evaluated to enable a decision to be made concerning the surgical prognosis. The Q-tip test is reproducible {LE4}. However, this Q-tip test is not well-correlated with urethral mobility measured by ultrasonography or urethrocytography {LE3}. Poor urethral mobility measured by the Q-tip test or urethrocytography is associated with a higher rate of failure for sub-urethral tape procedures {LE3}. Descent of point Aa in the POP-Q international prolapse classification is not a reliable method for quantifying cervico-urethral hypermobility and is not correlated with the diagnosis of stress urinary incontinence {LE3}.

It is recommended to assess urethral mobility prior to urinary incontinence surgery {Grade C}. It has not yet been established which is the best method for assessing urethral mobility.

Complete clinical assessment of stress urinary incontinence (loss of urine when coughing, laughing or exertion during questioning, a positive cough test, postvoid residual urine volume less than 50 ml, and functional bladder capacity above 400 ml according to the bladder diary) is well-correlated with the urodynamic findings {LE3}.

## **1.2 Urodynamic investigations**

The fact of carrying out an urodynamic investigation is not associated with better results for conservative treatment of female urinary incontinence {LE2}. Prescription of urodynamic investigations is not needed before lower urinary tract rehabilitation for female urinary incontinence {Grade B}.

Sub-urethral tape procedures for mixed urinary incontinence (with stress incontinence as the predominant symptom) without non-inhibited detrusor contraction found during the urodynamic work-up give results close to those observed for pure stress urinary incontinence {LE3}. Mixed urinary incontinence with urge incontinence predominating, or the presence of detrusor contractions found during cystometry, reduce the success rates with sub-urethral tape procedures {LE3}. Sphincter deficiency found during the urodynamic work-up is not a decisive prognostic factor for the result of a sub-urethral tape procedure {LE3}. A low urine flow rate preoperatively is associated with a higher risk of postoperative voiding dysfunction after sub-urethral tape procedure {LE3}. Urodynamic investigations are not capable of predicting postoperative urge incontinence {LE3}.

A complete urodynamic investigation is recommended prior to deciding on a surgical procedure to correct urinary incontinence {Grade C}. It is notably recommended to carry out an urodynamic investigation in the event of a previous surgical failure {PC}. In case of pure stress urinary incontinence, urodynamic investigations are not essential prior to surgery provided the clinical assessment is fully comprehensive (standardised questionnaire, cough test, bladder diary, establishment of postvoid residual volume) with concordant results {PC}. When the urodynamic work-up is carried out for urinary incontinence in an adult woman with no neurological problems, it should include a free uroflowmetry and a postvoid residual volume measurement, a filling and voiding cystometry, and a urethral profile including maximal urethral closure pressure measurement (MUCP) and Valsalva leak point pressure (VLPP) {Grade C}.



## **2 Treatment of female stress urinary incontinence**

### **2.1 Conservative treatment of female stress urinary incontinence**

Conservative treatment of adult female urinary incontinence includes pelvic floor physiotherapy, lifestyle and behavioural therapy, and medication.

#### 2.1.1 Treatment of female stress urinary incontinence by bladder or pelvic floor training

Bladder training is efficient for the treatment of female urinary incontinence with overactive bladder syndrome {LE1}. Pelvic floor muscle training give better results than no treatment for female urinary incontinence {LE1}. Vaginal electrostimulation for treatment of female stress urinary incontinence appears to have limited and inferior results compared with pelvic floor muscle training {LE2}.

It is recommended to start treatment for stress or mixed urinary incontinence with pelvic floor muscle training {Grade C}. Bladder training is recommended at first intention in cases with overactive bladder syndrome {Grade C}.

#### 2.1.2 Treatment of female stress urinary incontinence using oestrogen

Administration of oestrogen gives inhomogeneous results for urinary continence. Few low power trials with short follow-up have shown an impression of improvement in terms of leaks, which has not been confirmed in large follow-up studies including populations of incontinent or non-symptomatic women {LE1}. At the present time, therefore, the studies do not allow an optimum method of administration, dosage and type of oestrogen to be established for prevention or treatment of incontinence.

The benefits of oral oestrogen therapy alone or combined with progesterone have not been established for the prevention or treatment of urinary incontinence in postmenopausal women {LE2}. Vaginal oestrogen treatment improves urge incontinence and frequency {LE2}. Oral oestrogen treatment is not recommended for treatment or prevention of female stress urinary incontinence {Grade B}. Vaginal oestrogen treatment can be used in postmenopausal women to improve urge incontinence or frequency {Grade B}.

#### 2.1.3 Treatment of female stress urinary incontinence using duloxetine

Duloxetine is significantly better than the placebo for improvement of quality of life and of the perception of an improvement {LE1}. Case studies have shown a significant decrease in the number of leakage episodes of the order of 50% during the period of treatment {LE3}. However, on the basis of objective data, a meta-analysis of the pad-test with exertion and the

24-hour pad-test did not demonstrate any superiority for duloxetine compared with the placebo {LE1}. There are still no evidence whether there is a sustained efficacy during prolonged or after duloxetine administration.

The place of duloxetine in the treatment of female stress urinary incontinence is still not established, and this treatment is not recommended as a first line treatment of urinary incontinence {Grade B}.

#### 2.1.4 Treatment of female stress urinary incontinence by hygiene and dietary measures

For overweight patients, loss of weight improves stress urinary incontinence {LE1}. It is recommended to weigh every patient consulting for urinary incontinence and propose management associating dietary measures and physical exercise {Grade A}.

## **2.2 Surgical treatment at first intention for female stress urinary incontinence**

### 2.2.1 Surgical procedures

Among the many surgical techniques described to treat female stress urinary incontinence, the techniques used today are sub-urethral tapes (TVT, TOT) and retro-pubic colposuspension (Burch procedure by laparotomy or laparoscopy). Sub-urethral tape techniques and Burch colposuspension by laparotomy give comparable results for urinary continence {LE1}. Objective results for urinary incontinence obtained by laparoscopic colposuspension are slightly inferior to those obtained by sub-urethral tapes, but subjective results are comparable {LE1}. The postoperative course is simpler, shorter, and cheaper with sub-urethral tapes compared to Burch colposuspension by laparotomy or laparoscopy {LE1}.

Concerning sub-urethral tape techniques, the retropubic downside-to-top and topside-to-down routes give similar results {LE2}. The downside-to-top retropubic route gives better results in terms of continence than the transobturator route in case of sphincter deficiency {LE2}. The prepubic route is less efficient for urinary incontinence and involves a greater risk of complications than the other routes {LE2}. Transobturator routes inside-out or outside-in give similar results {LE2}. In the absence of any comparative studies, it is not possible to establish the place for sub-urethral minitapes to treat female urinary incontinence.

For female urinary stress incontinence surgery, sub-urethral tape (retropubic or transobturator route) is the first line recommended technique due to the simpler and shorter postoperative course than Burch colposuspension {Grade B}. Urethral sphincter deficiency does not contraindicate sub-urethral tape surgery {Grade B}. Concerning sub-urethral tape procedures,

both retropubic and transobturator routes have advantages, and it is not possible to recommend a preferred route {Grade B}. Modified sub-urethral tape techniques (minitapes, for example) need to be assessed by comparative clinical trials before being put into general practice {PC}. Surgeons should use implantable materials that comply with AFNOR standard S94-801 which guarantees that preclinical and clinical trials have been carried out prior to marketing {PC}.

Sub-urethral tapes procedures can be carried out under local, locoregional or general anaesthesia {LE1}. Sub-urethral tapes procedures are realisable on a day surgery or traditional hospitalisation basis depending on patient's and surgeon's preferences {Grade C}.

### 2.2.2 Sub-urethral tape complications

Sub-urethral tape surgery involves intraoperative risks, postoperative risks and a risk of failure which must be the subject of prior information for the patient {Grade A}. Risks such as erosion are specific to the use of non-absorbable materials. The CNGOF offers an information sheet destined for patients due to undergo stress incontinence surgery. Main intraoperative complications of sub-urethral tapes (in terms of frequency or severity) are vaginal, urinary and gastrointestinal tract injuries. Bladder injuries are less frequent with the transobturator than with the retropubic route {LE1}. Concerning the transobturator route, there is a greater risk of vaginal perforation in case of outside-in compared with inside-out passage {LE2}. Main postoperative complications with sub-urethral tapes are voiding dysfunction, urinary tract infection, urgency, pain, and vaginal, bladder or urethral erosion. The transobturator route gives more vaginal erosion than the retropubic route {LE1}. It is recommended to assess the quality of voiding postoperatively in order to screen for voiding dysfunction {Grade C}.

## **3 Particular circumstances**

### **3.1 Urinary incontinence during pregnancy and postpartum**

The prevalence of urinary incontinence symptoms increases during pregnancy (between the first and third trimester) then drops spontaneously during the first three months postpartum. This is true for stress and urge incontinence {LE1}. The existence of urinary incontinence prior to pregnancy or the appearance of urinary incontinence during pregnancy is a risk factor for continuation or appearance of urinary incontinence 3 months postpartum and later {LE1}.

Events of vaginal childbirth (position during birth, length of labour, duration of second phase, use of instruments for extraction, episiotomy, epidural or pudendal anaesthesia) have no impact on the appearance or persistence of urinary incontinence during the postpartum period or later {LE2}. At short term, birth by Caesarean section is associated with a lower prevalence and lower incidence of postnatal urinary incontinence {LE2}. At longer term there is insufficient data to draw conclusions {LE2}. Carrying out elective Caesarean section in case of breech presentation at full-term does not reduce the risk of stress urinary incontinence 2 years after birth {LE2}. In pregnant women who have already undergone surgery with sub-urethral tape, the frequency of postnatal urinary incontinence is not significantly reduced if the birth is by Caesarean section {LE4}.

In case of urinary incontinence during pregnancy and the immediate postpartum period, it is not recommended to carry out specialised investigations {Grade B}. Elective Caesarean section and systematic episiotomy are not recommended methods of prevention for postnatal urinary incontinence, including in women at risk {Grade B}.

Postnatal perineal rehabilitation including pelvic floor training under the direction of a therapist (re-educator or midwife) reduces the prevalence of urinary incontinence at short term (one year postpartum) compared with simple advice about individual pelvic floor exercises {LE1}. However the efficacy of this postpartum rehabilitation at long term has not been demonstrated {LE2}.

Perineal rehabilitation prescribed during pregnancy improves pregnancy urinary incontinence {LE1}, and reduces the frequency of urinary incontinence at 3 months postpartum {LE1}, but on the other hand it does not appear to have any benefits at longer term {LE2}.

Perineal rehabilitation by pelvic floor muscle training is the treatment of first intention for pre- and postnatal urinary incontinence {Grade A}. Preventive perineal rehabilitation is not recommended {Grade C}. Other treatments, whether medical or surgical, must not be proposed at first intention during pregnancy nor during the immediate postpartum period {Grade C}.

### **3.2 Urinary incontinence in elderly women**

The diagnostic and therapeutic approach to urinary incontinence in elderly women must take the age-related changes in the urinary tract and the fragility of the elderly person into account. Age is an independent risk factor for urinary incontinence {LE3}. The prevalence of urge incontinence increases with age. The predominant type of urinary incontinence in elderly

women is mixed urinary incontinence {LE1}. The number of voids at night increases with age in women, which can be explained in part by an increase in nocturnal diuresis {LE3}. The existence of postvoid residue is also more frequent {LE3}. If a bladder diary is not feasible, this is an indication of probable difficulty if not impossibility of management {LE4}.

Prior to any treatment decision for an elderly woman, it is recommended to screen for urinary infection using a test strip, ask for a bladder diary and measure postvoid residual volume {Grade C}.

Urinary incontinence in elderly women may be transient, encouraged by triggering factors liable to change, such as a confusion syndrome, a psychological factor, polymedication, excessive diuresis, reduced mobility or terminal constipation {LE2}. It is recommended to look for and if possible correct these triggering factors for urinary incontinence in elderly women {Grade B}.

Persistence of *de novo* urinary incontinence in an elderly woman despite correction of the triggering factors and rehabilitation management is a sign of vulnerability {LE2}. It is recommended to take advice of a geriatrician when vulnerability is identified {Grade C}. The main characteristics of a vulnerable elderly person are age over 85, polymedication, deterioration of cognitive functions, depression, undernutrition, neurosensorial problems, postural instability, lack of physical exercise, loss of independence with respect to every day activities, and social isolation.

The treatment possibilities for urinary incontinence are the same as for younger people when no vulnerability has been detected. For vulnerable, dependent elderly women, behavioural treatment with the help of a bladder diary gives results for diurnal incontinence that may be modest but present advantages due to the innocuity {LE4}. Elderly women who are heavily dependent from the cognitive and/or physical point of view should be managed by nursing methods: programmed voids, physical mobilisation and activity, use of suitable palliatives, regulation of bowel function {LE4}. Anticholinergics have been shown to be effective for urge or mixed incontinence in the female population aged over 65 {LE3}. In vulnerable elderly women, oxybutinin is less efficient for urge incontinence or urge-predominant mixed incontinence {LE3}. Severity of the incontinence, bladder hyposensitivity and cognitive deterioration are factors that reduce the response to treatment {LE2}. Anticholinergics may cause cognitive deterioration in elderly patients who did not suffer from this beforehand {LE2}. The association of anticholinergics with anticholinesterase, used to treat Alzheimer's disease, is not recommended.

Prescription of an anticholinergic for an elderly woman must be accompanied by monitoring for the appearance of deterioration in higher brain functions, constipation, urine retention or restricted food intake {Grade C}.

Desmopressin shows moderate efficacy for nocturia and nocturnal enuresis in incontinent and dependent elderly women {LE3}. It is often responsible for hyponatraemia in elderly people LE3. In France, desmopressin is not authorised for this indication for patients over 65.

### **3.3 Association or urinary incontinence and pelvic organ prolapse**

Pelvic organ prolapse commonly coexist with lower urinary tract symptoms such as stress urinary incontinence, urge incontinence, or obstructive symptoms. Urge incontinence or obstruction resolve in one out of two cases when the prolapse is corrected {LE2}. Pelvic organ prolapse may mask stress urinary incontinence in a proportion of women ranging from 20% to 70% of cases {LE3}. In women presenting with pelvic organ prolapse without stress urinary incontinence, rate of urodynamic stress incontinence detection is lower with pessary than with speculum prolapse reduction {LE1}. The pessary test has also been suggested to predict the result of prolapse surgery on urinary symptoms. In this indication the predictive value of the pessary test remains unclear {LE3}, and it is not recommended to use it routinely {Grade C}. A positive cough test and the screening of occult stress incontinence may identify patients with an increased risk of postoperative stress incontinence who could benefit from a concomitant anti-incontinence procedure at the time of pelvic organ prolapse surgery {LE4}. It is recommended to carry out a cough test and look for occult incontinence prior to surgery for pelvic organ prolapse {Grade C}. The preoperative urodynamic investigation has a predictive value for the postoperative risk of urge incontinence or voiding dysfunction in case of pelvic organ prolapse surgery {LE4}. It is recommended to carry out urodynamic investigations prior to pelvic organ prolapse surgery when there are urinary symptoms or occult urinary incontinence {Grade C}.

In continent patient who undergo sacrocolpopexy for pelvic organ prolapse carrying out a Burch colposuspension simultaneously reduces the risk of postoperative stress urinary incontinence {LE1}. In women with occult stress urinary incontinence, the association of a sub-urethral tape procedure at the time of prolapse surgery by vaginal route significantly reduces the rate of postoperative stress urinary incontinence {LE2}. Surgery for pelvic organ prolapse carried out simultaneously with sub-urethral tape procedure has no effect on the cure rate for stress urinary incontinence {LE2}.

In the absence of symptomatic or occult stress urinary incontinence there is no indication for carrying out a surgical procedure to prevent postoperative incontinence {Grade C}. In patient with combined surgery for pelvic organ prolapse and overt stress urinary incontinence, a Burch colposuspension or a sub-urethral tape are the two recommended surgical procedures {Grade C}. In case of pelvic organ prolapse surgery in a woman who also presents symptomatic or occult stress urinary incontinence, the decision to associate a surgical procedure for continence should be taken according to the severity of the stress urinary incontinence, the additional risk factors, the technique chosen and the foreseeable undesirable effects {PC}.

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