

Title:

Anterior repair using Bologna procedure:
Long-term results on stress urinary continence

Authors:

Xavier FRITEL, MD

Alain PIGNE, MD

Institution:

Unité d'urogynécologie, Service de Gynécologie et Obstétrique,
Hôpital Rothschild AP-HP,
Centre Hospitalier et Universitaire Saint-Antoine,
Université Pierre et Marie Curie, Paris, France

Correspondence:

Dr Xavier Fritel,
Service de Gynécologie et Obstétrique,
Hôpital Rothschild,
33 boulevard de Picpus, 75012 Paris, France
phone: +33.1.40.19.37.26
fax: +33.1.40.19.37.58
e-mail: xavier.fritel@rth.pa-hop-paris.fr

Anterior repair using Bologna procedure:

Long-term results on stress urinary continence.

Summary:

During anterior repair, one can use the redundant vaginal wall to make a sling under the bladder neck with good results for stress urinary continence.

Anterior repair using Bologna procedure:
Long-term results on stress urinary continence.

Abstract

Objective: To describe the prognostic factors and long-term results on stress urinary continence of the Bologna's procedure for bladder neck suspension in women undergoing vaginal repair for large cystocele.

Study Design: Cohort study and questionnaire based outcomes analysis.

Subjects: 218 women operated between 1982 and 1992. Mean age was 66 years.

Bologna's vaginal wall sling was associated with vaginal hysterectomy in 199 cases and posterior colporrhaphy in 202 cases.

Results: Median follow-up was 69 months. Of the patients, 182 were continent at stress (83%). The risk factors were low urethral pressure (< 30 cm H₂O, RR = 2.42), severity of preoperative stress urinary incontinence (RR = 2.01 for grade I, 4.03 for grade II, and 8.10 for grade III), and an exteriorized cystocele (RR = 0.45).

Conclusion: Bologna's procedure allows bladder neck suspension during vaginal repair of cystocele with good results on future continence.

Key words

Bladder neck suspension, Genital prolapse, Risk factor, Stress urinary incontinence.

Introduction

The surgical procedure described by Bolognaⁱ utilizes a sling under the bladder neck using two flaps coming from the vaginal anterior wall. In our institution, this procedure is used during the vaginal repair of genital prolapse with a large cystocele.ⁱⁱ The aim of this study is to determine the long-term outcome on stress urinary incontinence and to analyze the risk factors.

Methods

We identified 220 consecutive women suffering from a genital prolapse who underwent a vaginal repair with Bologna's procedure between January 1982 and December 1992. Complete medical records were available for 218 patients, who represent the study population.

In our institution, we perform a standardized and systematic preoperative assessment before any surgery for genital prolapse or urinary incontinence. This preoperative assessment includes a symptom specific questionnaire, a physical examination with prolapse staging and urinary stress test, and a urethral profilometry.

For the clinical staging of the SUI, we use the classification of Stameyⁱⁱⁱ: grade I for women who lose urine only with coughing, sneezing, or lifting heavy objects, grade II for those who lose urine with minimal activities such as walking or arising from the standing position, grade III for those who are totally incontinent in the upright position. Urge urinary incontinence is leakage related to a strong desire of voiding. Urinary incontinence is classified as others circumstances when leakage is not caused by stress or desire of voiding, for example during sleeping, after micturition, or without known circumstances.

The physical examination was performed in the lithotomy position with the trunk sat at 30° and the thighs flexed at 45°. The patients were hydrated (½ liter) one hour before the test. The genital prolapse was reduced and kept reduced with a Sim's speculum. The urinary stress test was positive if loss of urine was obtained after coughing or abdominal strain. The clinical staging of the genital prolapse was done at

maximal strain with an empty bladder. The three compartments of the prolapse (anterior, superior, and posterior) were examined separately. The prolapse was classified stage III when it was exteriorized, stage II when it stayed in the plane of the hymen, stage I when it stayed in the vagina, stage 0 when no prolapse was demonstrated. The bladder neck mobility was assessed visually. Bladder neck hypermobility was presumed when we demonstrated a frank mobility of the first centimeters of the anterior vaginal wall. Otherwise lateral cystourethrography was used when physical examination was not conclusive.

Urethral pressure profilometry was performed with a 2 side-hole catheter filled with sterile water. The genital prolapse was reduced during the profilometry. Methods, definitions, and descriptions conform to the standards recommended by the International Continence Society except where specifically noted.^{iv}

Bologna's original technique has been modified to be used in vaginal repair of genital prolapse. The principle of the procedure is to make a sling with two vaginal flaps passed on either side of the bladder neck. The principal steps of the procedure are as follows: The patient is placed in lithotomy position. A colpotomy is made between the bladder neck and the uterine cervix. Two vaginal flaps are cut in the anterior vaginal wall and free of the bladder (figure 1). Their lower ends remain attached to the vagina. Their free upper ends are passed through the prevesical space at either side of the bladder-neck and traverse the muscular abdominal wall (figure 2). A short skin incision made above the pubic symphysis permits catching the free upper ends of the flaps, which are fixed to

the muscular rectus aponevrosis. Cystoscopy ensures that the bladder has not been transfixed. Other vaginal surgical procedures for genital prolapse can be incorporated. The patients were asked to come for a postoperative visit at 1, 6 and 12 months for the first postoperative year and every year after. The postoperative evaluation included symptoms inventory, physical examination, and urodynamic findings in a manner identical to the preoperative evaluation.

The subjective outcome was assessed by a postal questionnaire sent in January 1995. The postal questionnaire was similar to the questionnaire used pre and postoperatively with the difference that it was self-administered. When there was no response to the first letter, a second questionnaire was sent. If this did not secure a response, we tried to reach the patient, the family or the general practitioner by phone. If the postal questionnaire was not completed, we used the questionnaire of the last postoperative visit to determine the outcome. The patient was considered free of stress urinary incontinence when she reported no leakage at stress. The anatomic outcome was assessed by the last postoperative visit. We used the postal questionnaire to ask if a recurrence of the genital prolapse had occurred. In the case of a positive response we considered the patient as an anatomic failure even if the last postoperative examination was normal. In the case of a negative response we still considered the patient as an anatomic failure if the last postoperative examination had demonstrated a genital prolapse stage II or III.

Statistical analysis was performed using χ^2 test for qualitative data, and Student's t test for quantitative data. Survival curves were analyzed using the Kaplan-Meier's

model and the logrank test. Confidence intervals were estimated using Rothman's formula. For the multivariate analysis, we used the Cox's model.

Results

Mean age was 66 years at surgery, 90% of the patients were 55 years old or older. The median parity was 2 and 5 patients had never given birth. Of the 23 patients who had had previous gynecologic surgery, 16 had a hysterectomy and 7 a vaginal reconstruction for genital prolapse. All patients had a genital prolapse, exteriorized in 169 cases (78%). The clinical examination, compartment by compartment, found a large cystocele (stage II or III) in 211 cases (97%), a major uterine prolapse (stage II or III) in 161 cases (74%), and a large rectocele (stage II or III) in 35 cases (16%). All patients had a bladder neck hyper mobility assessed by physical examination or cystourethrography. Urinary incontinence was reported by 97 patients (44%). Of the 88 patients with stress urinary incontinence (SUI), 51 were grade I, 30 were grade II, and 7 were grade III. For patients without symptomatic SUI, the stress test discovered a urinary incontinence in 24 of 128 (19%) if the prolapse was reduced. An exteriorized cystocele (stage III) was associated with an older age (67 years versus 63, $p = 0.009$), but was not associated with SUI, positive stress test or low urethral closure pressure. The grade of SUI was strongly associated with an urge incontinence: 5% (6/130) of urge incontinence for patients without SUI, 27% (14/51) for grade I, 33% (10/30) for grade II, and 86% (6/7) for grade III ($p < 0.0001$). The grade of SUI was not associated with the level of the urethral closure pressure.

All patients had the Bologna procedure. Vaginal hysterectomy was done in 199 cases (91%) and ablation of the residual cervix in 13 cases with previous abdominal

subtotal hysterectomy (6%). A vaginal posterior repair was performed in 201 cases (92%). The prevesical space was approached 4 times (2%) by the suprapubic incision to fix over-short flaps to the pectineal ligament. The median time for resumption of voiding (residual urine < 100 ml) was 10 days (4 to 35). Five patients were reoperated for a surgical complication: one vesicovaginal fistula, one peritonitis, one ureteral stenosis, one hematoma of the prevesical space and one missed swab. No mortality occurred during the first postoperative month. All patients came back for at least one postoperative visit. We did not encounter any vaginal epithelial inclusion cysts.

Outcome

We had 157 replies (72%) to the postal questionnaire (reply group). For the others patients (no-reply group): 15 (7%) were dead, 42 (19%) had moved, and 4 (2%) did not answer. The preoperative data (age at surgery, body mass index, parity, frequency, genital prolapse, urinary incontinence, profilometry) were similar between the reply group and the no-reply group. On the other hand, on the first of January 1995, the mean age of the no-reply group was 4 years higher (76 years versus 72, $p = 0.01$) and the mean period of time since surgery was 2 years higher (8.5 years versus 6.5, $p < 0.0001$ t test). Survival curves for postoperative SUI were similar between the reply group and the no-reply group with no statistical difference ($p = 0.34$ logrank test).

The median subjective follow-up was 69 months (1 to 163). At the last follow-up, 71 patients (33%) reported an urinary incontinence. The incontinence occurred in one or several circumstances: at stress for 36 patients (17%), in case of urge for 41 (19%) or in others circumstances for 14 (6%). The median time for recurrent SUI was 8 months (1 to 95). The estimated cumulative risk of recurrent SUI is 17% (95% CI: 12-23%) 5 years after the Bologna procedure (Figure 3). Three patients were reoperated for their incontinence, two colposuspension and one transurethral injection.^v The median objective follow-up was 32 months (1 to 161). At the last postoperative visit, the rate of positive urinary stress test was 10% (17/173). Thirty-two (15%) cases of anatomic relapse occurred, 24 cases of vaginal vault prolapse with enterocele, 5 cases of cystocele and 1 case of rectocele. In two cases the type of relapse was not stated because it occurred after the last examination. The estimated cumulative risk of recurrent genital

prolapse at 5 years is 15% (95% CI: 10-21). Fourteen patients were reoperated for their prolapse.

We used the survival curve and the logrank test for the univariate analysis of preoperative risk factors (Table I). The risk of suffering from SUI 5 years after surgery was higher in case of preoperative SUI (30% versus 8%), in case of preoperative urge urinary incontinence (44% versus 14%), and in case of urethral closure pressure lower than 30 cm H₂O (46% versus 15%). The 5 years risk of postoperative SUI was lower in case of preoperative exteriorized cystocele (12% versus 28%). For patients without symptomatic preoperative SUI, the 5 years risk of de novo SUI was similar in cases of positive or negative stress test (7.7% versus 8.5%).

After multivariate analysis, the variables that stayed significant were the preoperative grade of SUI, the exteriorized cystocele and the urethral closure pressure lower than 30 cm H₂O (Table II). Because the prognosis value of the variable "exteriorized cystocele" was not expected, we looked for others variables that could be forced into the Cox's model to eliminate the variable "exteriorized cystocele". We could not find any.

Discussion

With our policy of systematic and standardized preoperative assessment, data on each patient was collected prospectively. Unfortunately some useful investigations (menopausal status, pad test, cotton swab test, flow rate, cystometry, cystourethrography) were not uniformly performed in all cases.

A response rate of 72% to questionnaire was not unexpected as the patients lost to follow-up were aged (mean age at the time of the questionnaire: 76 years) and the surgery performed often many years in the past (mean delay: 8.5 years). The majority did not reply because they could not be reached, 15 were deceased and 42 had moved. Only 2% (4/218) did not return the questionnaire. We presumed that patients who had died or moved away would have the same recurrence rates for SUI that the patients who had replied to the questionnaire. The comparison of the survival-curve between the reply group and the no-reply group, confirmed this assumption.

Even when the patient is not symptomatic at stress, reducing the prolapse can reveal an occult incontinence (19% in our study). Urodynamic studies show that the urethral closure pressure declines when the prolapse is reduced.^{vi-ix} This is why, in the case of large anterior wall prolapse with bladder neck hypermobility, we prefer to perform a colposuspension even without symptomatic SUI. With this policy using Bologna's procedure, the risk of de novo SUI (patients without preoperative SUI) was only 8% five years after surgery. However, we cannot gauge the postoperative continence of these women had they not undergone the Bologna's procedure. It's difficult to estimate the prevalence of de novo SUI after prolapse surgery from the

literature. Borstad using the Manchester's procedure without anterior repair found that 22% of the women had de novo SUI.^x In a randomized study, Colombo found after prolapse surgery a subjective de novo SUI rate of 0% after Pereyra suspension versus 15% after pubourethral plication.^{xi}

For patients with preoperative SUI, we estimate that 70% would be continent at stress 5 years after surgery. Using the Bologna's procedure for 80 women with SUI and large cystocele, Giacalone found that 76% were free of SUI 3 years after.^{xii} That success rate compared favorably to other procedures used to cure SUI associated with large cystocele. Using Pereyra suspension, Colombo reported a subjective cure rate of 71% (15/21) with a mean follow-up of 6.7 years.^{xi} In a comparative study Giacalone found better results with Bologna than with Raz procedure (85 versus 35% of success rate at 2 years).^{xiii} Using pubovaginal sling associated to anterior repair, Cross observed 4 failures (11%) requiring recurrent surgery for SUI (mean follow-up: 20 months).^{xiv} Kelly plication alone had lower long-term success rates on SUI (almost 60%).^{xv-xvii}

Using multivariate analysis we found that preoperative low urethral closure pressure, grade of SUI and exteriorized cystocele had a prognostic value. Urethral closure pressure is known as a main prognosis factor in several surgical procedures for SUI. Our results show that the grade of SUI had a prognostic value, i.e. that it is easier to cure mild SUI than severe SUI using the Bologna procedure. Other authors observed similar evidence using anterior repair, needle suspension or Burch procedure.^{xvii-xix} The prognosis value of a preoperative exteriorized cystocele was unexpected. In our study, a patient with a large cystocele had a lower risk of postoperative incontinence. An

exteriorized cystocele was more frequent when age increased. But when we forced the variable “age” into the Cox’s model it did not change the prognostic value of the variable “exteriorized cystocele”. The vaginal flaps may be wider and perhaps tougher in case of large cystocele.

Some vaginal epithelial inclusion cysts had been reported after vaginal wall sling procedure.^{xx} With Bologna procedure this adverse effect had never be reported.^{ii, xii}

Bologna procedure is effective to treat stress incontinence among patients with a large cystocele. Risk factors for failure are severe SUI, low urethral closure pressure, and mild cystocele.

Acknowledgments:

We are grateful to Mark Bambury, Dr Patrice Commegeille, Armelle Eveillard, Dr Arnaud Fauconnier and Pr Alastair MacLeynard for help and advice. And we thank Elsevier for giving us permission to copy free two drawings.

References

- i Bologna U. A new surgical procedure for the correction of urinary stress incontinence in the female. *Urol Int* 1978;33:150-8
- ii Pigné A, Boyer de Latour F, Keske J, et al. Traitement des prolapsus uro-génitaux avec incontinence urinaire d'effort par l'intervention de Bologna, à propos de 90 cas. *J Gynecol Obstet Biol Reprod* 1988;17:379-86
- iii Stamey TA. Endoscopic suspension of the vesical neck for urinary incontinence in female: reports of 203 consecutive patients. *Ann Surg* 1980;192:465-471
- iv Abrams P, Blaivas JG, Stanton SL, Andersen JT. The International Continence Society Committee on Standardisation of Terminology: the standardisation of terminology of lower urinary tract function. *Scand J Urol Nephrol* 1988;114S:5-19
- v Barranger E, Fritel X, Kadoch O, Liou Y, Pigné A. Results of transurethral injection of silicone micro-implants for female with intrinsic sphincter deficiency. *J Urol* 2000;165:1619-1622.
- vi Richardson DA, Bent AE, Ostergard DR. The effect of uterovaginal prolapse on urethrovesical pressure dynamics. *Am J Obstet Gynecol* 1983;146:901-5
- vii Veronikis DK, Nichols DH, Wakamatsu MM. The incidence of low-pressure urethra as a function of prolapse-reducing technique in patients with massive pelvic organ prolapse (maximum descent at all vaginal sites). *Am J Obstet Gynecol* 1997; 177:1305-13

-
- viii Bergman A, Koonings PP, Ballard CA. Predicting postoperative urinary incontinence development in women undergoing operation for genitourinary prolapse. *Am J Obstet Gynecol* 1988;158:1171-5
 - ix Bump RC, Hurt WG, Theofrastous JP, et al. Randomized prospective comparison of needle colposuspension versus endopelvic fascia plication for potential stress incontinence prophylaxis in women undergoing vaginal reconstruction for stage III or IV pelvic organ prolapse. *Am J Obstet Gynecol* 1996;175:326-35
 - x Borstad E, Rud T. The risk of developing urinary stress-incontinence after vaginal repair in continent women. A clinical and urodynamic follow-up study. *Acta Obstet Gynecol Scand* 1989;68:545-9
 - xi Colombo M, Maggioni A, Scalabrino S, Vitobello D, Milani R. Surgery for genitourinary prolapse and stress incontinence: a randomized trial of posterior pubourethral ligament plication and Pereyra suspension. *Am J Obstet Gynecol* 1997;176:337-43
 - xii Giacalone P-L, Laffargue F, Daures J-P, Lombard I. The Bologna bladder neck suspension procedure for treatment of stress urinary incontinence associated with cystocele. *Int Urogynecol J* 1998;9:370-8
 - xiii Giacalone P-L, Laffargue F, Daures J-P, Lombard I, Lombard G. Incontinence urinaire d'effort féminine, comparaison de la technique de Raz et de la technique de Bologna, analyse d'une série de 188 patientes. *J Gynecol Obstet Biol Reprod* 1998;27:309-18

-
- xiv Cross CA, Cespedes RD, McGuire EJ. Treatment results using pubovaginal slings in patients with large cystoceles and stress incontinence. *J Urol* 1997;158:431-4
 - xv Glazener CMA, Cooper K. Anterior vaginal repair for urinary incontinence in women. In: *The Cochrane Library*, Issue 2, 2000
 - xvi Weber AM, Walters MD. Anterior vaginal prolapse: review of anatomy and techniques of surgical repair. *Obstet Gynecol* 1997;89:311-8
 - xvii Tamussino KF, Zivkovic F, Pieber D, Moser F, Haas J, Ralph G. Five-year results after anti-incontinence operations. *Am J Obstet Gynecol* 1999;181:1347-5
 - xviii van Geelen JM, Theeuwes AG, Eskes TK, Martin CB Jr. The clinical and urodynamic effects of anterior vaginal repair and Burch colposuspension. *Am J Obstet Gynecol* 1988;159:137-44
 - xix Nitti VW, Bregg KJ, Sussmann EM, Raz S. The Raz bladder neck suspension in patients 65 years old and older. *J Urol* 1993;149:802-7
 - xx Woodman PJ, Davis GD. The relationship of the in-situ advancing vaginal wall sling to vaginal epithelial inclusion cyst. *Int Urogynecol J* 2000;11:124-126

Table I. Preoperative risk factors and estimation of the survival without stress urinary incontinence (SUI) at 5 years. Kaplan-Meier survival curve and logrank test.

Preoperative Risk Factors		Subjects (number)	Free of SUI at 5 years (95% CI)	logrank p value
Age at surgery, years	< 60	21% (46/218)	76 % (61-86)	.15
	≥ 60	79% (172/218)	85 % (78-90)	
Body mass index, kg/m ²	< 25	66% (119/181)	86 % (78-92)	.12
	≥ 25	33% (62/181)	78 % (65-87)	
Parity	0-1	22% (49/218)	83 % (68-91)	.70
	2-3	52% (113/218)	82 % (73-88)	
	4-10	26% (56/218)	86 % (73-94)	
Voiding frequency / 24h	< 8	64% (135/211)	82 % (74-88)	.61
	≥ 8	36% (76/211)	84 % (73-91)	
Exteriorized cystocele	No	33% (72/218)	72 % (60-82)	.02
	Yes	67% (146/218)	88 % (82-93)	
Pads	No	86% (188/218)	85 % (78-89)	.08
	Yes	14% (30/218)	72 % (51-86)	
Urinary incontinence	No	56% (120/218)	91 % (84-95)	.002
	Yes	44% (98/218)	73 % (62-81)	
Stress urinary incontinence	No	60% (130/218)	92 % (85-96)	.0006
	Grade I	23% (51/218)	75 % (60-85)	
	Grade II	14% (30/218)	67 % (48-82)	
	Grade III	3% (7/218)	54 % (21-83)	
Urge urinary incontinence	No	83% (182/218)	86 % (79-91)	.01
	Yes	17% (36/218)	66 % (48-81)	
Others urinary incontinence	No	88% (192/218)	84 % (77-89)	.08
	Yes	12% (26/218)	73 % (50-87)	
Maximal urethral closure pressure, cm H ₂ O	≥ 30	88% (192/218)	85 % (79-90)	.03
	< 30	12% (26/218)	64 % (41-82)	
Functional urethral length, mm	< 25	38% (82/216)	80 % (70-88)	.75
	≥ 25	62% (134/216)	84 % (76-90)	

Table II. Multivariate analysis for postoperative stress urinary incontinence (SUI). Final model.

Preoperative risk factor		Relative Risk for Postoperative SUI (95% CI)
SUI	No	1
	Grade I	2.01 (0.88-4.60)
	Grade II	4.03 (1.69-9.63)
	Grade III	8.10 (2.24-29.33)
Exteriorized Cystocele	No	1
	Yes	0.45 (0.23-0.88)
Maximal urethral closure pressure cm H ₂ O	≥ 30	1
	< 30	2.42 (1.08-5.42)

Figure legends

Figure 1. Two vaginal flaps are cut in the anterior vaginal wall [Pigné A, Serment G. Chirurgie de l'incontinence urinaire d'effort. Editions scientifiques et médicales Elsevier SAS. Tous droits réservés. Techniques chirurgicales Urologie-Gynécologie, Paris, 41830, 1992].

Figure 2. The free ends of each vaginal flap are passed at either side of the bladder-neck [Pigné A, Serment G. Chirurgie de l'incontinence urinaire d'effort. Editions scientifiques et médicales Elsevier SAS. Tous droits réservés. Techniques chirurgicales Urologie-Gynécologie, Paris, 41830, 1992].

Figure 3. Postoperative cumulative survival curve without stress urinary incontinence (time scale in months).