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Burch Procedure Compared With Sling for Stress Urinary Incontinence: A Decision Analysis

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Objective: To compare the relative risks and benefits of Burch colposuspension and sling procedure for primary genuine stress urinary incontinence in women.

Methods: We developed a decision analytic model to compare Burch procedure and sling for primary surgical treatment of genuine stress incontinence with urethral hypermobility in women. Risks and benefits were estimated from published literature. The main outcome measure was effectiveness of treatment, defined as cure of incontinence after initial and secondary treatments. We considered four outcomes of primary surgical treatment: cure, persistent incontinence (either caused by intrinsic sphincter deficiency without urethral hypermobility or genuine stress incontinence with hypermobility), de novo detrusor instability, and permanent urinary retention. Secondary treatment included repeated surgery for genuine stress incontinence, collagen injection for intrinsic sphincter deficiency, medical treatment for detrusor instability, and urethrolisis for retention. One-way sensitivity analyses were used to estimate the effect of varying each characteristic through its range; all other characteristics were fixed at their baseline values.

Results: The overall effectiveness of Burch and sling operations (percentages of women cured after initial and secondary treatments) was similar (94.8% and 95.3%, respectively). In sensitivity analyses, the Burch arm of the model was more effective than sling when the risk of retention after

sling was higher than 9.0% or when the risk of de novo detrusor instability after sling was higher than 10.3%. Conversely, when the risk of de novo detrusor instability after Burch was higher than 6.8%, the sling arm of the model was more effective.

Conclusion: The Burch and sling procedures are similarly effective for primary surgical treatment of genuine stress incontinence in women. Overall effectiveness is substantially influenced by relative rates of complications. (Obstet Gynecol 2000;96:867-73. © 2000 by The American College of Obstetricians and Gynecologists.)

There is no consensus on the best operation for women with genuine stress urinary incontinence and urethral hypermobility. Although deficiencies in the surgical literature on stress incontinence have been highlighted,¹ on the basis of indirect¹⁻³ and direct⁴ comparative evidence from the literature, it is generally accepted that anterior repairs and needle suspension procedures are less effective than retropubic (Burch) colposuspensions and sling procedures. Experts in the field have provided strong opinions for and against sling procedures in women with genuine stress incontinence and urethral hypermobility, with different estimates of risk and benefit to support their arguments.^{5,6} Without data

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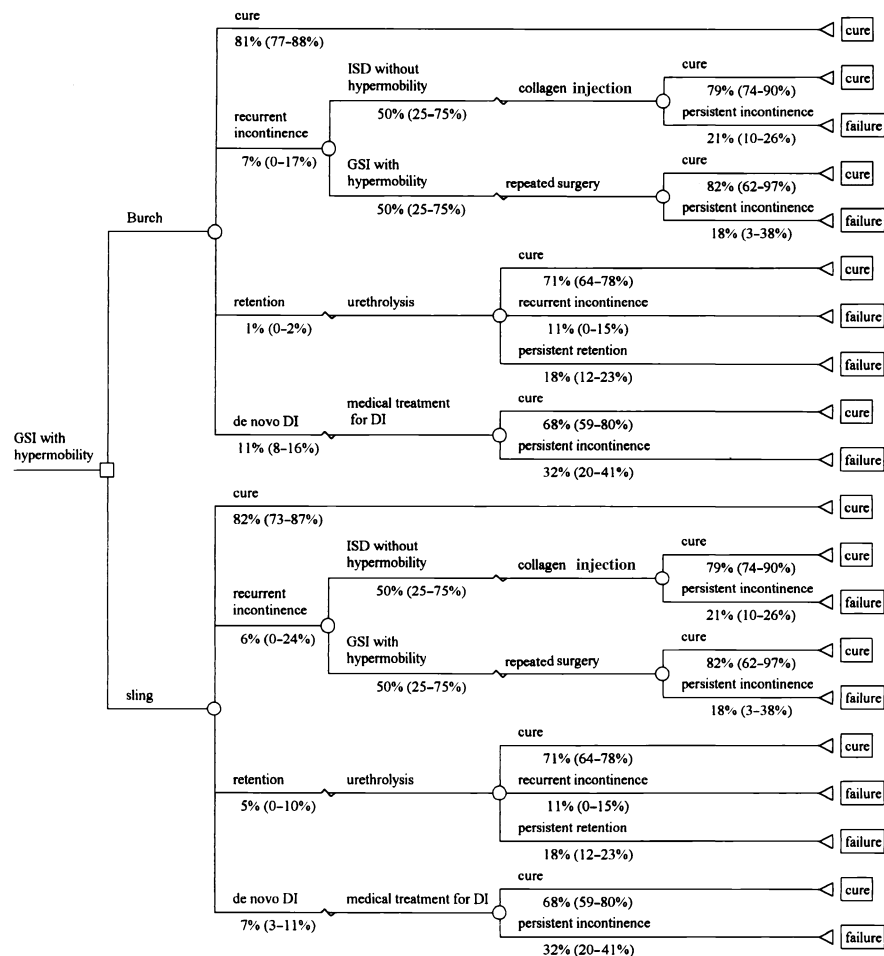


Figure 1. Decision analytic model comparing effectiveness of Burch colposuspension and sling procedure for primary genuine stress urinary incontinence with urethral hypermobility. The number listed under the characteristic is the baseline estimate; the range is in parentheses. DI = detrusor instability; GSI = genuine stress incontinence; ISD = intrinsic sphincter deficiency.

from randomized controlled trials, clinicians are uncertain about which is better.

Decision analytic models can be used to formalize decision making and identify key factors. Sensitivity analyses can identify factors that influence the outcome. Our objective was to use decision analysis to compare the relative risks and benefits of Burch colposuspension with sling procedure for primary genuine stress incontinence with urethral hypermobility in women.

Materials and Methods

Our decision analytic model (Figure 1) was developed in two steps. We defined a hypothetical population of women with genuine stress urinary incontinence and urethral hypermobility for whom primary surgery was planned. Women with primary diagnoses of intrinsic sphincter deficiency were excluded. Burch colposuspension or sling procedure was then done, and outcomes (resolution of incontinence, need for retreatment

for incontinence or complications, and cost) were estimated. The decision analytic model included the first treatment and a second series of evaluation and treatments for women who were not cured initially.

For the model and the literature review, we defined incontinence procedures according to the Agency for Health Care Policy and Research Clinical Practice Guideline for Urinary Incontinence in Adults.³ For Burch colposuspension, the vaginal wall lateral to the urethra and bladder neck is elevated toward the Cooper ligaments on each side in the retropubic space. The sling procedure involves placing a sling made of autologous or heterologous material under the urethrovesical junction and anchoring it to retropubic or abdominal structures.

The main outcome measure was effectiveness of treatment, defined as cure of incontinence, and we calculated average cost per cure as a secondary outcome. We considered four outcomes of primary surgical treatment: cure, persistent stress incontinence (caused

Table 1. Estimates in the Decision Analytic Model Comparing Burch Colposuspension and Sling Procedure

Estimate	Range	Definition	Study, Year (Quality, Grade)*
Outcome of treatment			
81%	77–88%	Cure rate of GSI after initial Burch	Leach et al, ² 1997 (B) Fantl et al, ³ 1996 (B)
82%	73–87%	Cure rate of GSI after initial sling	Leach et al, ² 1997(B) Cross et al, ⁷ 1998 (B) Litwiller et al, ⁸ 1997 (B)
82%	62–97%	Cure rate of GSI after repeated surgery	Leach et al, ² 1997 (B) Fantl et al, ³ 1996 (B)
79%	74–90%	Cure rate of incontinence after collagen injection for ISD	McGuire and Appell, ⁹ 1994 (B) Eckford and Abrams, ¹⁰ 1991 (B) Herschorn et al, ¹¹ 1992 (B) Stricker and Haylen, ¹² 1993 (B) Cross et al, ¹³ 1998 (B)
68%	59–80%	Cure rate of medical treatment for DI	Karram and Bhatia, ¹⁴ 1989 (B) Bent, ¹⁵ 1990 (B) Fantl et al, ¹⁶ 1981 (A) Moore et al, ¹⁷ 1990 (A) Riva and Casolati, ¹⁸ 1984 (A)
Retention			
1%	0–2%	Rate of permanent retention after initial Burch	Leach et al, ² 1997 (B)
5%	0–10%	Rate of permanent retention after initial sling	Leach et al, ² 1997 (B) Cross et al, ⁷ 1998 (B) Cross et al, ¹⁹ 1997 (B) Wright et al, ²⁰ 1998 (B)
71%	64–78%	Cure rate after urethrolisis for retention	Goldman et al, ²¹ 1999 (B) Carr and Webster, ²² 1997 (B) Nitti and Raz, ²³ 1994 (B) Austin et al, ²⁴ 1996 (B) Cross et al, ²⁵ 1998 (B) Foster and McGuire, ²⁶ 1993 (B) McGuire et al, ²⁷ 1989 (B)
11%	0–15%	Rate of recurrent incontinence after urethrolisis for retention	Goldman et al, ²¹ 1999 (B) Nitti and Raz, ²³ 1994 (B) Austin et al, ²⁴ 1996 (B) Cross et al, ²⁵ 1998 (B) Foster and McGuire, ²⁶ 1993 (B) McGuire et al, ²⁷ 1989 (B)
18%	12–23%	Rate of persistent retention after urethrolisis for retention	Goldman et al, ²¹ 1999 (B) Nitti and Raz, ²³ 1994 (B) Austin et al, ²⁴ 1996 (B) Cross et al, ²⁵ 1998 (B) Foster and McGuire, ²⁶ 1993 (B) McGuire et al, ²⁷ 1989 (B)
Other			
11%	8–16%	Probability of de novo DI after initial Burch	Leach et al, ² 1997 (B)
7%	3–11%	Probability of de novo DI after initial sling	Leach et al, ² 1997 (B)
50%	25–75%	Probability of GSI with urethral hypermobility as cause of recurrent incontinence after initial Burch	(C)
50%	25–75%	Probability of ISD without urethral hypermobility as cause of recurrent incontinence after initial Burch	(C)
50%	25–75%	Probability of GSI with urethral hypermobility as cause of recurrent incontinence after initial sling	(C)
50%	25–75%	Probability of ISD without urethral hypermobility as etiology of recurrent incontinence after initial sling	(C)

DI = detrusor instability; GSI = genuine stress incontinence; ISD = intrinsic sphincter deficiency.

* Quality of references are graded as follows: (A) controlled trials, (B) clinical series, (C) expert opinion.

by genuine stress incontinence with urethral hypermobility or intrinsic sphincter deficiency without hypermobility), incontinence caused by de novo detrusor

instability, and permanent urinary retention. Secondary treatment included repeated surgery for genuine stress incontinence with hypermobility, collagen injection for

Table 2. Cost Estimates in the Decision Analytic Model Comparing Burch Colposuspension and Sling Procedure*

Estimate	Definition
\$4491	Cost of initial Burch or sling
\$4642	Cost of repeated Burch or sling
\$5012	Cost of urethrolisis
\$965	Cost of collagen injection
\$138	Cost of medical treatment for detrusor instability
\$2680	Cost of caring for persistent incontinence for 1 y
\$2348	Cost of caring for persistent retention for 1 y

* See text for details of cost estimation.

intrinsic sphincter deficiency, medical treatment for detrusor instability, and urethrolisis for retention. Outcomes after secondary treatment were cure, persistent incontinence, and urinary retention. For persistent incontinence after two unsuccessful surgical procedures and unsuccessful medical treatment for detrusor instability, costs of 1 year of management were estimated, including routine care (absorbent products) and health consequences of incontinence (eg, skin breakdown). For persistent retention after urethrolisis, costs of 1 year of intermittent self-catheterization were estimated. To simplify the model, other complications of surgery and complications of testing or medical treatment were not included.

Parameter estimates were collected from articles identified by performing a MEDLINE search from 1966 to 1999, supplemented by references in articles collected through MEDLINE (Table 1).^{2,3,7-27} Each article was reviewed for data on outcomes after treatment of women with stress urinary incontinence. The quality of evidence was rated by using the following system:³ (A) properly designed and implemented controlled trials; (B) properly designed and implemented clinical series; and (C) expert opinion. The literature review was performed to identify the range of reported outcomes rather than include all published reports on each characteristic. Baseline characteristics were calculated by averaging reported proportions. Highest and lowest reported values were used as ranges for sensitivity analyses. Characteristics for which no data could be found were estimated by consensus of authors and were varied by at least $\pm 25\%$ for sensitivity analyses. Length of reported follow-up varied; however, for the purposes of the model, we assumed that the cure rate was stable for at least 1 year.

Costs (not charges), shown in Table 2, were calculated by using reported methods.²⁸ Costs were collected from the 1998 Federal Register on the basis of coding from Medicare diagnosis-related groups and International Classification of Diseases, 9th revision (ICD-9). Costs for hospital services were calculated by using diagnosis-related group case weights multiplied by standard urban rates for labor, nonlabor costs, and capital. Costs for physician services were calculated by

using relative value units for specific tests and procedures multiplied by a standard conversion factor. Costs for outpatient tests and procedures included facility costs and professional reimbursement. Cost of medical treatment was based on twice-daily administration of oxybutynin for 1 year.

Decision analysis and sensitivity analyses were performed in two steps. We considered all probabilities and costs to be fixed and calculated actual expected mean effectiveness (cure rate of incontinence) and costs for each algorithm. We then conducted a series of sensitivity analyses to estimate the impact of each characteristic on the results. We assessed the effect of systematically changing each characteristic through its range while holding other parameters constant at their baseline values (one-way sensitivity analyses). For each value of the designated characteristics, the mean effectiveness for Burch and sling were compared. Threshold analyses were done to identify the characteristic's value that would change the results; if needed, ranges were extended beyond their original bounds to calculate threshold values. All modeling, calculations, and sensitivity analyses were done with DATA 3.0 (TreeAge Software Inc., Williamstown, MA), a decision analysis software program.

Results

Using baseline characteristics in the decision analytic model, the overall effectiveness of treatment (cure rate of incontinence after initial and secondary treatments) was similar at 94.8% for Burch colposuspension and 95.3% for sling procedure. Presented another way, in a hypothetical population of 1000 women, 948 would be cured in the Burch arm of the model compared with 953 in the sling arm. The average cost per successful out-

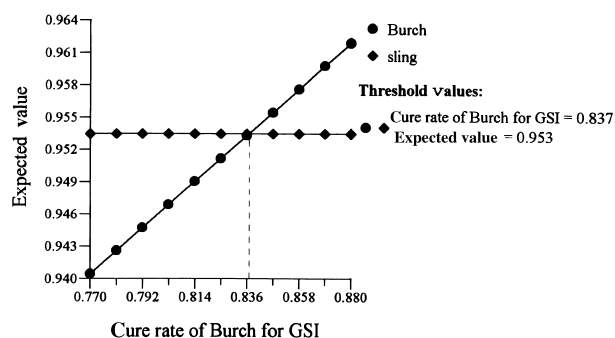


Figure 2. One-way sensitivity analysis demonstrating the threshold value of 83.7% (dashed line) for the estimated probability of cure after Burch colposuspension for genuine stress incontinence (GSI). If the cure rate after Burch was lower than 83.7%, the overall effectiveness (cure rate of incontinence after initial and secondary treatments [expected value]) of the sling procedure arm of the model was higher than that of the Burch arm of the model. Conversely, if the cure rate after Burch was higher than 83.7%, the effectiveness of Burch was higher. The overall effectiveness of the Burch and sling arms of the model was equivalent when the cure rate after Burch equaled 83.7%.

come, which included the costs of initial and secondary treatments and outcomes, was similar (\$4891 for Burch procedure and \$5041 for sling).

One-way sensitivity analyses identified several variables that influenced the relative effectiveness of the two arms of the model. The overall effectiveness of the Burch colposuspension arm of the model compared with sling increased as the estimated cure rate of incontinence after initial and repeat Burch increased. As shown in Figure 2, Burch colposuspension was favored over sling if the cure rate with initial Burch was greater than 83.7%. The Burch arm also was favored when the cure rate after repeated Burch was greater than 97.0%. Sling was favored over Burch if the cure rate of initial sling was greater than 78.7% (Figure 3) or if the cure rate with repeated sling was greater than 71.5%. As seen on the Y axis (expected value) in Figures 2 and 3, the overall effectiveness varied by approximately two percentage points (94–96%) across the entire range of estimated cure rates for both Burch and sling. Relatively large changes in cure rate for initial treatment resulted in only small changes in overall effectiveness.

Varying the risk of de novo development of detrusor instability after surgery also influenced results. When the probability of de novo detrusor instability after sling was greater than 10.3%, effectiveness of the Burch arm was higher than that of the sling arm (Figure 4). When the probability of de novo detrusor instability after Burch was greater than 6.8%, the sling arm of the model was favored (Figure 5). Determining the threshold for the probability of de novo detrusor instability after Burch required an extension of the range beyond our original estimates (original range, 8–16% [Table 1]). Also, relatively large changes in probability of de novo

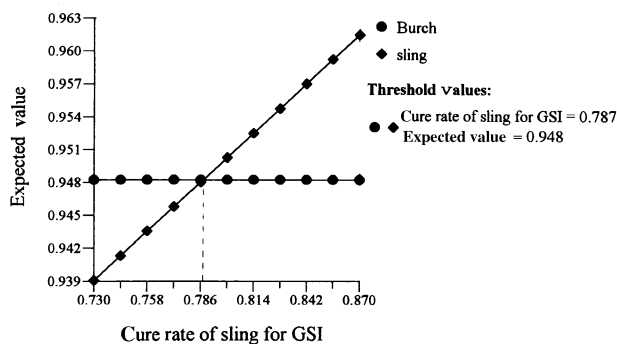


Figure 3. One-way sensitivity analysis demonstrating the threshold value of 78.7% (dashed line) for the estimated probability of cure after sling procedure for genuine stress incontinence (GSI). If the cure rate after sling was lower than 78.7%, the overall effectiveness (cure rate of incontinence after initial and secondary treatments [expected value]) of the Burch colposuspension arm of the model was higher than that of the sling arm of the model. Conversely, if the cure rate after sling was higher than 78.7%, the effectiveness of sling was higher. The overall effectiveness of the Burch and sling arms of the model was equivalent when the cure rate after sling equaled 78.7%.

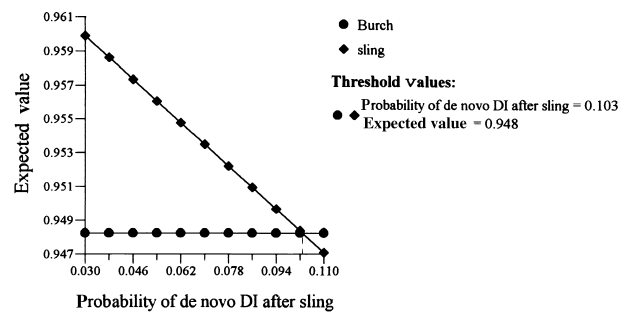


Figure 4. One-way sensitivity analysis demonstrating the threshold value of 10.3% (dashed line) for the estimated probability of de novo detrusor instability (DI) after sling procedure. If the risk of de novo DI after sling was lower than 10.3%, the overall effectiveness (cure rate of incontinence after initial and secondary treatments [expected value]) of the sling arm of the model was higher than that of the Burch colposuspension arm of the model. Conversely, if the risk of de novo DI after sling was higher than 10.3%, the effectiveness of Burch was higher. The overall effectiveness of the Burch and sling arms of the model was equivalent when the risk of de novo DI after sling equaled 10.3%.

detrusor instability after either procedure resulted in small changes in overall effectiveness.

The results of the model were sensitive to varying the probability of retention after sling (but not to varying the probability of retention after Burch). As shown in Figure 6, when the risk of retention after sling was lower than 9.0%, the overall effectiveness of the sling arm of the model was higher than Burch. However, if the risk of retention after sling was higher than 9.0%, the Burch arm was favored.

Sensitivity analyses identified only two other variables that influenced results. The sling arm of the model was favored if the cure rate after urethrolysis (ie,

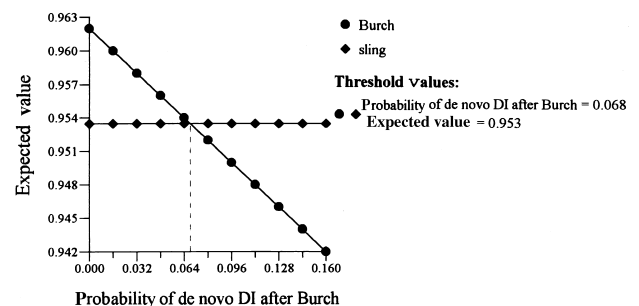


Figure 5. One-way sensitivity analysis demonstrating the threshold value of 6.8% (dashed line) for the estimated probability of de novo detrusor instability (DI) after Burch colposuspension. If the risk of de novo DI after Burch was lower than 6.8%, the overall effectiveness (cure rate of incontinence after initial and secondary treatments, [expected value]) of the Burch arm of the model was higher than that of the sling procedure arm of the model. Conversely, if the risk of de novo DI after Burch was higher than 6.8%, the effectiveness of sling was higher. The overall effectiveness of the Burch and sling arms of the model was equivalent when the risk of de novo DI after Burch equaled 6.8%.

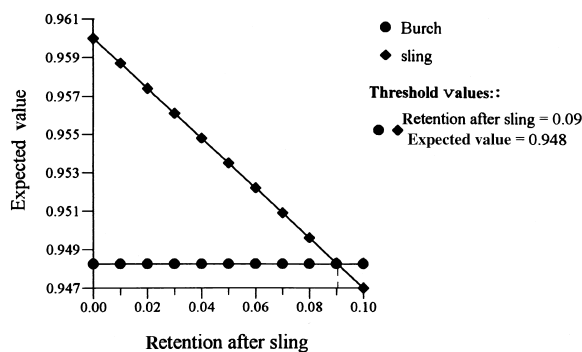


Figure 6. One-way sensitivity analysis demonstrating the threshold value of 9.0% (dashed line) for the estimated probability of retention after sling procedure. If the risk of retention after sling was less than 9.0%, the overall effectiveness (cure rate of incontinence after initial and secondary treatments [expected value]) of the sling arm of the model was higher than that of the Burch colposuspension arm of the model. Conversely, if the risk of retention after sling was higher than 9.0%, the effectiveness of Burch was higher. The overall effectiveness of the Burch and sling arms of the model was equivalent when the risk of retention after sling equaled 9.0%.

resolution of retention and maintenance of continence) was higher than 57.9%. When the cure rate of medical treatment for detrusor instability was greater than 81.1%, the Burch arm was favored. Results were not influenced by varying estimated cure rates of incontinence after collagen therapy for intrinsic sphincter deficiency or by varying the estimated probability of genuine stress incontinence with hypermobility or intrinsic sphincter deficiency without hypermobility as the cause of recurrent incontinence after initial Burch or sling.

Discussion

Various operations have been developed for treating genuine stress incontinence, and there is no consensus on the best operation. The ideal surgical procedure should be effective and long lasting and pose low risks to women. It appears that the two most effective types of surgical procedures are retropubic colposuspension and the sling procedure. In a systematic review published in 1996 of the effectiveness of surgery for stress incontinence in women, Black and Downs¹ reported that, on the basis of limited data, colposuspension appeared to be more effective and long lasting than anterior colporrhaphy or needle suspension. In the few comparative studies, Burch colposuspension and sling procedure had similar outcomes, regardless of whether they were done as primary or secondary (repeated) procedures. Black and Downs noted that all studies had low power to detect clinically significant differences,¹ and further research was needed to resolve the issue.

Using decision analytic modeling, we compared the effectiveness and cost of Burch colposuspension and

sling procedure for primary surgical treatment of genuine stress incontinence. Our model was designed to examine benefits (cure) and complications (recurrent incontinence, detrusor instability, and urinary retention) and their effects on primary and secondary cure rates and cost. Most clinical reports have examined only the rates of cure of individual operations, perhaps with additional information on certain variables that affect cure rates. However, the outcome of importance for surgery is not merely initial cure; to assess effectiveness, complications, their treatments, and effectiveness of secondary treatments must be considered. This allows us to better understand overall effectiveness of an operation and how it affects important measures, such as quality of life and cost.

In this decision analysis, we addressed one of the prime controversies of the sling procedure and Burch colposuspension: that higher or equal cure rates of sling procedures compared with Burch are achieved in association with higher rates of such complications as urinary retention and detrusor instability.⁵ Sensitivity analyses showed that if the rate of permanent urinary retention after a sling procedure was lower than 9%, as in most series,^{2,7,19,20} the overall effectiveness of the sling arm of the model was higher than that of the Burch. If the probability of detrusor instability for either operation was greater than about 6–10%, effectiveness of the other procedure would be higher. The quantification of those variables is extremely important, not only when considering the literature but in planning correct surgical procedures on the basis of surgeons' personal rates of outcomes and complications.

The major limitation of our study was that it relied on published literature on effectiveness of surgery for stress incontinence. The methodologic quality of those data is generally poor.¹ Nevertheless, because the reported cure rates for Burch and sling were similar, estimates of the characteristics used in the base case analysis of the model did not influence results. Sensitivity analyses determined the thresholds at which results would be affected; higher cure rates for either procedure would favor that procedure. If subsequent studies show substantially different cure rates for Burch and sling, the model's results could be different. However, the differences would have to be substantial. Even relatively large changes in characteristic estimates resulted in small changes in overall effectiveness.

Decision analytic models represent simulated events with several simplifying assumptions, and the results are based on averages. They do not address the full range of individual clinical issues. For example, in our model, urethrolisis was used for women in retention after sling or Burch. Experienced clinicians recognize that some women with intractable postoperative voiding dysfunction without complete retention might benefit from urethrolisis, which was not included in the model. In theory, it is not necessary to limit the number

of possibilities included in these models. In reality, limitations and assumptions are necessary for practical purposes in creating a workable model.

Few data are available on complications after incontinence surgery, effectiveness of treatment of complications, and frequency and effectiveness of secondary treatments. As of 1996, only about 800 women have been randomly assigned to undergo surgical treatment of stress incontinence, and those studies had methodologic faults. Solid data from large, high-quality prospective studies are urgently needed to document outcomes after incontinence surgery, such as the cause of recurrence after Burch colposuspension or sling procedure and short-term and long-term complications. In addition, randomized controlled trials directly comparing Burch and sling procedures should be done. We are well aware of the difficulty of randomized trials of surgical treatments; however, it is essential that such studies be done. Until those studies have been completed, recommendations on the best clinical practice cannot be based on direct scientific evidence. In the meantime, our decision analysis might help individual surgeons decide on the best treatments for women on the basis of their individual or group cure rate and rate of complications.

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