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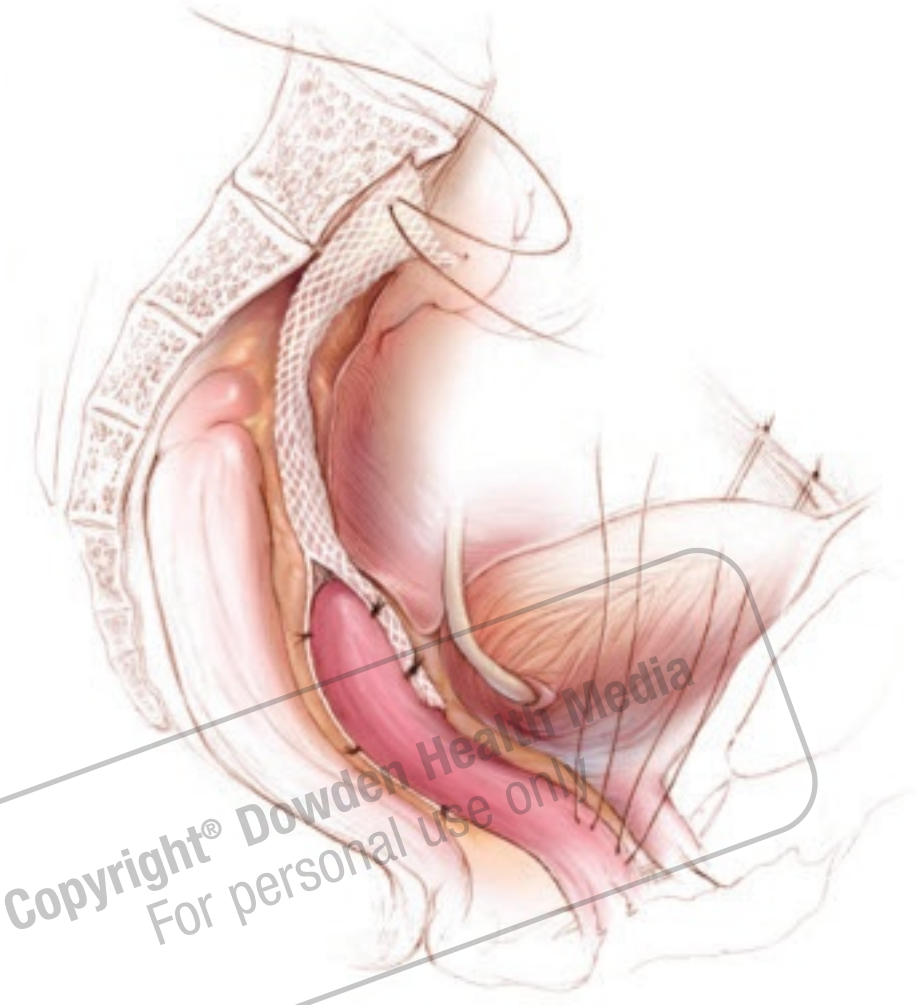

When the periurethral vaginal tissue is sutured to the iliopectineal ligaments at the time of abdominal sacrocolpopexy, it stabilizes the urethra and prevents postoperative stress incontinence in a significant number of women.

IMAGE: KIMBERLY MARTENS

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Things go better with Burch

CARE trial: Burch colposuspension at the time of prolapse surgery improves postop urinary control

Why should we care about the CARE (Colpopexy and Urinary Reduction Efforts) trial?

Because pelvic organ prolapse and urinary incontinence are already major problems facing women as they age, and will become even more pervasive as the baby boomer generation moves through menopause and beyond.

Because the risk that a woman will experience stress incontinence after prolapse surgery ranges from 8% to 60%.[1–6]

Because roughly one third of women who undergo prolapse or incontinence surgery require a second operation.

These are just a few of the factors that spurred the Pelvic Floor Disorders Network to undertake the CARE trial, published April 13 in the *New England Journal of Medicine*. OBG MANAGEMENT convened a panel of experts in female pelvic medicine, including 2 CARE trial investigators, to discuss the findings of this landmark study, its long-term implications, and the future of research into pelvic floor disorders.

How the trial was conducted

The CARE trial involved 322 women who required surgery to correct pelvic organ prolapse (POP) but lacked symptoms of stress urinary incontinence. All these women underwent sacrocolpopexy, an

abdominal procedure in which graft material is attached between the vagina and sacrum to support the vagina and correct the prolapse. These women were randomized to undergo Burch colposuspension at the time of the sacrocolpopexy, or to undergo sacrocolpopexy only. The Burch procedure is performed through the same incision as the sacrocolpopexy and involves suturing the periurethral vaginal tissue to the iliopectineal ligaments on each side, providing urethral support.

Enrollment in the trial was halted after the first of 2 planned interim analyses because the frequency of postoperative stress incontinence was significantly lower in the group undergoing Burch colposuspension: 23.8% and 44.1% of women in the Burch and no-Burch groups, respectively, experienced stress symptoms by 3 months after the surgery.

Why the CARE trial is an epochal event

- **First randomized trial of preventive incontinence surgery in women with prolapse**
- **Randomized design establishes cause and effect**
- **Subjects will be followed for 2 years**

KOHLI: Dr. Brubaker, as lead investigator of the CARE trial, how would you characterize the study's major strengths?

BRUBAKER: First, it is a well-designed, randomized, controlled trial and thus provides the highest level of evidence for clinical practice. Although there is no perfect study, this one minimized the risk of bias by involving multiple centers (7) and using multiple surgeons, making the findings more generalizable than would be the case in a single-surgeon case series.

In addition, the use of blinded urodynamic testing lent strength, because the ability of urodynamic testing to predict the need for a concomitant continence procedure was not known before the trial. Our follow-up manuscript, containing data presented at the recent Society of Gynecologic Surgeons meeting, will provide more details on this aspect of the trial.

WEBER: Randomized trials are held in such high esteem—provided all other aspects of study design and implementation are performed properly—because they support conclusions of cause and effect. The conclusion that Burch colposuspension prevents stress incontinence when performed at the time of abdominal sacrocolpopexy could only be drawn from a randomized trial.

Trial design standardized key elements

Many types of bias confound the results of nonrandomized studies, particularly selection bias (eg, when surgeons select which procedure to perform on the basis of patient characteristics), and valid conclusions of cause and effect cannot be drawn. However, with a randomized trial, subjects are separated into groups by chance and

OUR EXPERT PANELISTS

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"The research community is reaching a consensus that 'subjective' measures are more important than objective measures"

—Anne M. Weber, MD

no other factor. Thus, the groups are equivalent at baseline—provided the sample size is large enough (and allowing for random differences)—and therefore any changes measured after the experimental intervention can be confidently attributed to the intervention itself.

Another strength of the trial is standardization. The subjects were "standardized" by rather broad inclusion and exclusion criteria to constitute an important clinical population and to ensure they were sufficiently similar so that the treatment (abdominal sacrocolpopexy) was appropriate for all. In addition, surgeons at the multiple participating sites agreed to standardization of the technical details of the Burch colposuspension so that the subjects received the same intervention regardless of site. And data collection in follow-up was performed in a standard way by research staff who were blinded to the subjects' group assignment (intervention versus control), so the data were as free of bias as possible.

Homogeneous study population may be a weakness

KOHLI: I agree that the methodology of this well-designed study is its major strength. What are its weaknesses?

WEBER: No doubt there are several, only some of which may be apparent at this time. For example, most women in the study were Caucasian, and very few were Hispanic, Asian, or black. Although we have no scientific reason to believe that Burch colposuspension has different responses in women of different racial and ethnic backgrounds, the trial's subjects are not diverse enough to analyze the data by subgroups to confirm or refute the hypothesis that response to the Burch procedure is independent of race or ethnicity.

BRUBAKER: Another weakness: Because this study was closed after the first interim analysis, some of our secondary analyses will be underpowered, although we clearly demonstrated a difference in our primary endpoint.

It is important to remember that this study is not "finished." Our participants are still in active follow-up for 2 years following surgery. It will be interesting to see what happens during the longer follow-up, especially with regard to prolapse and incontinence. We are also doing additional in-depth analyses of urodynamic and other parameters.

KOHLI: Again, I think the study design and analysis were well thought out. It would have been interesting to see how the results broke down according to site, to see if there was variation—which could indicate variation in surgical technique.

BRUBAKER: We have not done this analysis and do not plan to at this time.

Why paravaginal repairs were allowed

KOHLI: What about the decision to include surgeries that involved paravaginal repair?

WEBER: That generated a fair amount of discussion during trial design, as there was no clear "right" answer. Perhaps it would have been "cleaner" to eliminate the option of performing paravaginal repair, but when the trial was designed, we lacked unequivocal evidence that paravaginal repair at the time of abdominal sacrocolpopexy provides additional support for the anterior vagina. Therefore, we decided to allow the decision to be based on surgeon judgment.

Some surgeons perform paravaginal repair with abdominal sacrocolpopexy in almost all women because they believe quite strongly that this reduces the risk of recurrent anterior vaginal prolapse. Others never perform paravaginal repair with abdominal sacrocolpopexy and feel just as strongly that their patients are adequately treated and protected from subsequent anterior vaginal prolapse.

Investigators feared paravaginal repairs could dilute Burch effects

Study surgeons did agree that paravaginal repair reduces the likelihood of postoperative stress incontinence, although not as effectively as Burch colposuspension. Thus, our dilemma: If paravaginal repairs were performed in a large number of subjects, thereby improving their postoperative continence status regardless of whether Burch

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"This study is not 'finished.' Our participants are in active follow-up for 2 years following surgery"

—Linda Brubaker, MD, MS

was performed, the effect of Burch could be so diluted as to be lost. On the other hand, if paravaginal repairs were completely excluded, that would restrict some surgeons' practices and potentially reduce the number of women who would be offered participation in the study if their surgeons felt their anterior vaginal prolapse would be potentially undertreated.

We resolved the dilemma as follows:

1. A relatively low proportion—about one quarter—of surgeons performed paravaginal repairs regularly with abdominal sacrocolpopexy, so the potential impact in the trial would not be great.
2. Paravaginal repairs were allowed, but only when declared necessary by the surgeon before randomization; this step prevented surgeons from changing their minds about the necessity of paravaginal repair if the subject was assigned to the Burch group (ie, the woman would be receiving additional anterior vaginal support by way of the Burch).
3. We stratified for paravaginal repair in the randomization, so women with paravaginal repair were equally distributed between the intervention and control groups.

Are subjective or objective measures better?

- **Subjective measures convey a patient's foremost concerns and how she is doing clinically**
- **Correlating symptoms with objective measures yields valuable insights into treatment**

KOHLI: The CARE trial uses both objective and subjective measures of incontinence. Which do you think are most important?

BRUBAKER: I prefer subjective measures because I think they reflect what is most important to patients in quality-of-life disorders. However, I believe we need to understand the relationship between subjective outcomes and traditional "objective" outcomes.

WEBER: I think the research community is reaching a consensus that "subjective" measures—better described as patient-oriented outcomes—are more important than objective measures, particularly for conditions that affect patients in "subjective" ways, ie, ways that affect their health-related quality of life, rather than quantity of life. This does not mean that objective measures are useless—although we should first evaluate each measure critically to make that determination on the basis of evidence.

Nevertheless, when a patient seeks and receives treatment based on symptoms and how those symptoms impact her daily life, I think it is incumbent upon researchers and clinicians to ensure that the treatment that is considered most effective actually results in a change that the patient finds worthwhile.

What is "success"?

WALTERS: When it comes to incontinence, for which there is an imperfect correlation between various objective and subjective measures, I think both types of measures are valuable and important. Gathering several different types of outcomes for each patient helps us better understand the nuances of how well an intervention works.

I can understand why some clinicians and researchers place greater reliance on subjective measures of incontinence, such as a diary of incontinence episodes and quality-of-life measures, because these measures tell us exactly how the patient is doing clinically and how she feels about the intervention. If she reports that she is completely cured and "perfect," then objective measures are irrelevant. However, for any subjective outcome short of perfect, correlation with the objective measures such as cough stress test, physical examination, and urodynamic tests can help investigators understand the reason for the imperfect outcome and point to areas of possible improvement.

KOHLI: In my practice, some women who continue to leak slightly after an incontinence procedure consider their surgery a

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"Patients who are continent preoperatively, but become stress-incontinent postoperatively, are particularly unhappy"

—Mark D. Walters, MD

complete success, whereas, as a surgeon, I consider it a suboptimal result. Both objective and subjective results are important.

Putting the CARE trial into practice

- **Data relate directly only to women undergoing abdominal sacrocolpopexy**
- **Patient education, medicolegal, and reimbursement may also relate**
- **Results reflect the high prevalence of pelvic floor disorders and the need to routinely ask about them**

KOHLI: How will the CARE trial findings affect your clinical practice?

BRUBAKER: I routinely counsel patients who are planning sacrocolpopexy but who do not have stress incontinence to consider a concomitant Burch procedure. I do not have them undergo urodynamic testing because, at this time, the results of that testing would not change my clinical practice.

WALTERS: I have always been liberal when it comes to adding retropubic colposuspension to abdominal sacrocolpopexy, even in women who do not have preoperative stress incontinence. The reason? Patients who are continent preoperatively, but become stress-incontinent postoperatively, are particularly unhappy with their outcome, especially if they need another surgery within a year to treat the stress incontinence. So this study verified what I was already doing.

What I didn't learn is whether a paravaginal defect repair helps or hurts the Burch procedure from an anatomic and functional perspective.

It also appears that preoperative urodynamic testing has little value, although that was not the point of this study. I am glad it will be addressed in future studies.

KOHLI: I think the findings apply to those select patients undergoing abdominal sacrocolpopexy for prolapse. It would be dangerous to extrapolate these results to other abdominal vault suspension procedures or vaginal prolapse procedures. Based on the CARE trial, I plan to counsel patients about the risks and benefits of "optional" Burch colposuspension at the time of planned sacrocolpopexy. In reality, however, I have almost completely switched to minimally invasive midurethral slings, even in the case of abdominal prolapse procedures, because of their high cure rates, low complication rates, and ease of postoperative adjustment.

Clinical implications depend on surgeon's routine

KOHLI: What are the implications for the majority of ObGyns?

WEBER: It depends on what ObGyns are doing for women with prolapse.

For ObGyns who are confident and competent, through training and experience, to perform abdominal sacrocolpopexy for women with advanced prolapse, the CARE trial results have a direct effect. Women with prolapse who are stress continent with no contraindications, can be reassured that they will benefit from a 50% reduction of postoperative stress incontinence with the Burch procedure.

For ObGyns who do not perform sacrocolpopexy, the CARE trial will have no direct clinical effects. Nevertheless, these clinicians need to be aware of the findings so they can discuss the options with patients before decisions on route or type of prolapse surgery are made.

The CARE trial and its results remind us of the high prevalence of pelvic floor disorders in women, potentially even after corrective surgery—and the need to actively screen all women for pelvic dysfunction.

Warn of potential incontinence even with the Burch

KOHLI: How does this study affect counseling of candidates for prolapse surgery?

BRUBAKER: I would offer stress-continent women a Burch procedure at the time of sacrocolpopexy. That much is clear. The interesting discussions come from "similar" clinical scenarios, where data are not yet available. For example, should a stress-

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"Even when Burch colposuspension was performed, a number of women still had urinary incontinence after surgery"

—Anne M. Weber, MD

continent woman facing a suspension via the vaginal route undergo a concomitant continence procedure?

WEBER: It is important to keep in mind that even when Burch colposuspension was performed, a number of women still experienced urinary incontinence (some stress, some urge, some mixed) after surgery; and the vast majority of women have urinary symptoms of some kind both before and after surgery. So preoperative counseling should include the information that urinary symptoms are very common after abdominal sacrocolpopexy—some as persistent or recurrent, and some as new symptoms.

As longer follow-up data from the CARE trial become available, we will learn how many women have urinary symptoms that are temporary versus long-lasting.

Is routine Burch best?

- **When not all women benefit, should a procedure be offered prophylactically? In this case, experts say, "Yes"**
- **Some physicians favor other incontinence procedures**
- **Final decision rests with the patient**

KOHLI: Based on study numbers, 100 Burch procedures at the time of abdominal sacrocolpopexy would be necessary to prevent 20 women from developing incontinence. Is that a fair equation?

WALTERS: It is an easy decision for me. As I said earlier, women are particularly unhappy if they go from continent to incontinent after a surgery. In fact, some women are more displeased with that outcome than with a failure of the prolapse surgery. Because most women with prolapse have substantial anterior vaginal wall prolapse, the Burch procedure—with or without a paravaginal defect repair—also serves as part of the prolapse repair of the anterior wall. And now we know it also improves postoperative urinary function.

BRUBAKER: Doing a Burch procedure at the time of sacrocolpopexy is a time-efficient and low-morbidity addition, so it is worthwhile for me and my patients. It is clearly not the same as doing a secondary, stand-alone procedure for new symptoms.

Over the next 2 years, we will see how many women who were moderately or greatly bothered by stress incontinence went on to a surgical treatment.

WEBER: Please note a careful distinction: I would be willing to *recommend* Burch colposuspension to 100 stress-continent women who are planning to undergo abdominal sacrocolpopexy for prolapse, with the expectation that this will prevent postoperative stress incontinence in roughly half the women who would have developed it otherwise. It is up to the patient to accept this recommendation or not.

Based on the CARE trial results, 44 of 100 previously continent women after only abdominal sacrocolpopexy develop postoperative stress incontinence, compared with about 24 of 100 women after Burch and abdominal sacrocolpopexy. Even more striking is the difference in women affected by bothersome stress incontinence: almost 25% in the control group versus 6% in the Burch group. Women in the Burch group did not experience an excess of adverse events, or a clinically significant difference in operative time or estimated blood loss, compared with women in the control group.

Is "wait and see" better?

KOHLI: Because I favor minimally invasive midurethral sling procedures, which can often be performed on an outpatient basis under local anesthesia, I counsel women undergoing prolapse surgery via an abdominal or vaginal route that it is best to treat the incontinence postoperatively if it occurs. Obviously, this applies to women who have no incontinence and do not demonstrate potential stress incontinence on urodynamic testing preoperatively.

Anecdotally, I have not found a high rate of new-onset urinary incontinence following prolapse procedures. We may retrospectively look at these patients more

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"Doing a Burch procedure at the time of sacrocolpopexy is a time-efficient and low-morbidity addition"

—Linda Brubaker, MD, MS

critically in light of this new data.

WALTERS: I think most women would be dissatisfied with a 44% risk of postoperative stress incontinence requiring a second surgery. Even if you counseled them appropriately, many women would ask that you try to manage everything at the first surgery.

What are nonclinical effects of the trial?

- **Need for patient and physician education is great, and the CARE trial offers a valuable opportunity**
- **Potential for medicolegal risk if complications develop**
- **Payers may not be willing to reimburse for a prophylactic procedure**

KOHLI: Are there any nonclinical issues that arise from application of the study's conclusions—such as medicolegal, financial, or educational issues?

WEBER: Given how extensively the trial's results were disseminated by the lay press, I think we have an important opportunity to educate both patients and health-care providers.

First, patients: For women who may be directly affected by the trial, knowledgeable clinicians should explain its results and limitations to help them reach a decision about their treatment.

For women who hear the trial's results described incompletely or incorrectly (eg, "…2 stitches prevent incontinence…"), clinicians should take this opportunity to correct misunderstandings and educate women about incontinence, prolapse, and pelvic health in general.

For health-care providers, this trial reminds us of the extraordinarily high prevalence of pelvic floor disorders. Although current treatments are not perfect, virtually all women with pelvic floor disorders can be treated to substantially alleviate, if not eliminate, bothersome symptoms.

All clinicians should routinely inquire about pelvic symptoms and be prepared to initiate an evaluation or provide a referral.

Medicolegal fallout?

KOHLI: There is the question of medicolegal risk if complications occur after colposuspension when the patient had no complaints or evidence of stress incontinence at the time of preoperative urodynamic testing. I am not aware of any legal precedent in which a clinical study or data provided solid protection from a jury verdict. The study did not show increased risk or complication with the addition of the Burch procedure, but that may not be true for some surgeons and some patients.

Billing and coding

In terms of billing, how should we code for the Burch colposuspension when the patient had no demonstrable stress incontinence? Payment denials in this scenario seem likely. This may create a line of separation between what may be clinically indicated for the patient and what insurance companies are willing to pay for.

There may be the option to use the urethral hypermobility code (ICD 599.81) for the Burch colposuspension, but only time will tell if this will be reimbursed. I would be curious to hear the panel's experience with reimbursement for a prophylactic procedure based on scientific data. Obviously, what is best for the patient is most important.

BRUBAKER: All these patients had urethral hypermobility, which is also an indication for a Burch colposuspension.

Is preoperative urodynamic testing useful?

- **CARE trial data still to come**
- **Basic testing is probably helpful**

KOHLI: Is urodynamic testing necessary for women undergoing prolapse surgery?

WEBER: In the CARE trial, the relative level of protection from postoperative stress

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"I think most women would be dissatisfied with a 44% risk of postoperative stress incontinence requiring a second surgery"

—Mark D. Walters, MD

incontinence provided by the Burch procedure did not depend on the stress-test component (with prolapse reduced) of preoperative urodynamic testing. About 50% fewer women had postoperative stress incontinence after Burch, whether preoperative urodynamic testing showed positive or negative stress tests with prolapse reduction.

Although subsequent analyses (presented at the Society of Gynecologic Surgeons 2006 meeting; manuscript under review) focused on urodynamic testing and postoperative outcomes, the CARE trial was not designed primarily to determine whether women planning prolapse surgery benefit from preoperative urodynamic testing. Therefore, conclusions about the "need" for urodynamic testing should not be based only on the CARE trial.

Should urodynamic testing determine treatment?

Randomized trials that directly address the cost-benefit of urodynamic testing are urgently needed. For now, as is standard in good clinical practice, a test should be performed only if results will change recommendations or provide reliable and clinically important prognostic information about a patient's outcome after intervention. Clinicians should determine whether urodynamic testing meets even 1 of these 2 minimum criteria.

I want to point out that the CARE trial did not address the utility of urodynamic testing.

BRUBAKER: It is clear that some women have stress incontinence despite the concomitant Burch colposuspension. If we learn that an alternative operation can perform better and that any urodynamic (or other clinical measure) can predict improved outcomes, I would consider resuming urodynamic testing.

WALTERS: At first glance, it appears that complex urodynamic testing is definitely not necessary if the goal is to improve outcomes of surgery. However, I believe the patient should undergo some components of urodynamic testing such as a void with a post-void residual urine volume and a basic bladder-filling study noting sensation and capacity. I also do a cough stress test with the prolapse reduced, although we may find that this does not predict postoperative function.

KOHLI: The results of this study are very procedure-specific. If similar results are borne out when other approaches to prolapse and incontinence are analyzed, the value and utility of preoperative uro-dynamic testing in all patients may be questionable.

However, in my practice, I use the results of preoperative urodynamic testing not only for diagnosis, but also to make subtle adjustments when performing incontinence procedures—especially in regard to suburethral slings.

What if you prefer midurethral slings?

- **Surgeons should be comfortable with more than 1 incontinence procedure**
- **We should not jump to untested conclusions**

KOHLI: How does application of the CARE trial's conclusions change if the physician is currently performing midurethral sling procedures for incontinence?

WEBER: Ideally, well trained and experienced gynecologic, urologic, or urogynecologic surgeons perform more than 1 type of incontinence procedure, to meet the needs of different patients.

As yet, we have no direct, evidence-based answers to issues such as these:

Can a midurethral sling be substituted for a Burch colposuspension and have the same average results in preventing post-operative stress incontinence without increasing urgency symptoms …

- … when abdominal sacrocolpopexy is performed for prolapse in a preoperatively stress-continent patient?

At present, all a clinician can do is reflect on data from case series of midurethral sling procedures for incontinence, and guess at the outcome when used as pro-

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"All clinicians providing care for women should routinely inquire about pelvic symptoms"

—Anne M. Weber, MD

phylaxis and combined with abdominal sacrocolpopexy.

- … when vaginal apical suspension is performed for prolapse in a preoperatively stress-continent patient?

I think the critical issue remains how the midurethral sling will perform when it is used for prophylaxis instead of treatment. As with the Burch, the most important clinical concern is the creation or worsening of urgency or other irritative bladder symptoms. When this occurs in the treatment setting, it may be acceptable to the patient and clinician. In the setting of prophylaxis, however, I doubt it would be acceptable.

Although it is tempting to jump 1 or 2 steps ahead and apply CARE trial data to situations that have not been tested directly, I would be cautious. We want to avoid creating long-lasting or refractory urgency symptoms—especially in a woman who had no such symptoms before surgery—because of a prophylactic procedure.

I think this is especially true because it is relatively easy to salvage patients who do develop bothersome stress incontinence after prolapse surgery.

Bonus: Burch helps anterior vaginal prolapse

WALTERS: I wonder whether prophylactic placement of a midurethral sling would yield the same results as a prophylactic Burch procedure. If your midurethral sling of choice is a tension-free vaginal tape (TVT), I would be cautious about placing it prophylactically, because the TVT has a 2% to 3% risk of prolonged voiding dysfunction requiring transection of the tape.

However, it is possible that prophylactic placement of a transobturator sling, which is associated with much less voiding dysfunction and fewer major surgical complications, might have a different outcome—though this requires further study.

In addition, midurethral slings would not be as effective as Burch colposuspension in treating anterior vaginal prolapse, so I would expect to see more anterior wall prolapse failures if slings replaced colposuspension.

What if you prefer the vaginal approach?

Further study is needed

KOHLI: Since many, if not most, gynecologists surgically treat prolapse and incontinence using a vaginal approach, how does the CARE trial affect their practice?

WALTERS: I wonder whether a prophylactic transobturator midurethral sling at the time of transvaginal prolapse repair would yield similar results. I do cystocele repair with suburethral ("Kelly") plication, which seems to work well at stabilizing the urethra in women without stress incontinence. But this approach is not as popular these days, and future studies may demonstrate that a prophylactic midurethral sling will result in better long-term function without significantly increasing the long-term risk.

WEBER: The CARE trial results are relevant to all pelvic surgeons because they demonstrate the need for and benefit from well-designed randomized surgical trials. Another benefit will be extended follow-up in what will become a prospective cohort study of women with advanced prolapse treated by abdominal sacrocolpopexy—providing higher-quality evidence than retrospective case series. Although not as valuable as randomized trials, these data can help guide clinical recommendations.

If long-term results support the effectiveness and durability of abdominal prolapse repair, then gynecologists can reflect on the evidence and choose the approach that best fits the patient's needs.

Need for other studies?

Randomized, multicenter trials addressing almost any surgical treatment of prolapse and incontinence are sorely needed

KOHLI: What other possible multicenter clinical studies involving prolapse/incontinence would you suggest?

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"I am not aware of any legal precedent in which a clinical study or data provided solid protection from a jury verdict"

—Neeraj Kohli, MD, MBA

BRUBAKER: Any and all high-quality, well-designed trial can improve our care of women with incontinence and/or prolapse.
WALTERS: I look forward to the follow-up studies from the CARE trial on the value of paravaginal defect repair, preoperative urodynamic testing, and the efficacy of various prolapse-reduction maneuvers in predicting surgical outcomes.

It would also seem logical to repeat this type of study using transvaginal prolapse repair with or without a prophylactic midurethral sling. Another option: anterior colporrhaphy with suburethral plication versus a prophylactic midurethral sling.
KOHLI: I look forward to data on surgical procedures currently being performed with greater frequency despite a lack of good-quality data. These include the transobturator suburethral midurethral sling procedures, laparoscopic sacrocolpopexy, and vaginal mesh augmentation for prolapse.

The Pelvic Floor Disorders Network affords a unique opportunity to perform well-designed multicenter trials to address the rapidly changing landscape of surgical treatment for prolapse and incontinence. ■

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