

## Recent literature with comments

### Uterine artery embolisation is a major step forward

Dutton S, Hirst A, McPherson K, Nicholson T, Maresh M. A UK multicentre retrospective cohort study comparing hysterectomy and uterine artery embolisation for the treatment of symptomatic uterine fibroids (HOPEFUL study): main results on medium-term safety and efficacy. *BJOG*. 2007; 114: 1340–51

*Objectives:* Comparison of medium-term safety and efficacy of hysterectomy and uterine artery embolisation (UAE) for symptomatic uterine fibroids.

*Study design:* Multicentre retrospective cohort including 459 women who had hysterectomy within a national audit during 12 months from October 1994 (VALUE study; average follow up of 8.6 years) and 649 women receiving UAE from 1996 to 2002 (average follow up of 4.6 years). Main outcome measures included complication rates, side effects of embolisation, satisfaction with treatment, relief from symptoms and requirement for further fibroid treatment.

*Results:* Fewer complications were experienced by women receiving UAE (19 versus 26% hysterectomy,  $P=0.001$ ); the adjusted odds ratio for UAE versus hysterectomy was 0.48 [95% confidence interval (CI), 0.26–0.89]. One third of women undergoing UAE experienced anticipated general side effects associated with the procedure. More women in the hysterectomy cohort reported relief from fibroid symptoms (95 versus 85%,  $P<0.0001$ ) and feeling better (96 versus 84%,  $P<0.0001$ ), but only 85% would recommend the treatment to a friend compared with 91% in the UAE arm ( $P=0.007$ ). There was a 23% (95% CI, 19–27%) chance of requiring further treatment for fibroids after UAE. Twenty-seven women who had had UAE reported 37 pregnancies after treatment resulting in 19 live births.

*Conclusions:* UAE results in fewer complications than hysterectomy. Side effects after embolization should be anticipated, and almost one quarter of women having UAE

were likely to require further treatment for fibroid symptoms. Both treatments appear to be safe and effective over the medium term, and the choice of treatment may be a matter of personal preference for each individual woman.

### COMMENTARY

This study describes the results of a retrospective multivariate statistical cohort study comparing safety and efficacy of hysterectomy and uterine artery embolisation. The article must be considered as recommended to read.

Uterine artery embolisation is considered to be less invasive than classical hysterectomy for the treatment of uterine fibroids. After uterine artery embolisation, fertility is preserved and uneventful pregnancies are reported. Hysterectomy is a final and definitive treatment option.

In this study, data were analysed of 1,122 (63.9%) women collected from 1,734 eligible subjects for this study. More than 5 years were analysed in 46.5% of the embolisation cohort and 86.7% of the hysterectomy cohort. The authors give minimal information about the large number of patients who did not respond and the effects on outcome.

However, the results reported show a significant fewer complication rate in the embolisation cohort than in patients after hysterectomy. One quarter requires follow-up treatment for fibroids after the initial embolisation procedure.

The hysterectomy cohort report relief of symptoms significantly more often than the embolisation cohort, although significantly more women would recommend embolisation as the treatment of choice.

Uterine artery embolisation has the purpose of preventing surgical removal of the uterus, thus preserving uterine functions, while on the other hand, surgical removal does not preserve any function of the uterus and bears the disadvantage of disturbance of anatomical integrity of the body caused by surgery. Quality of life must be investigated prospectively and more explicitly in the future, giving

attention to psychological effects, sexual behaviour and satisfaction and general well-being after minimal and maximal invasive therapy. Comparison of embolisation of the uterine arteries for symptomatic fibroids within the other study arm using any treatment except for hysterectomy can provide the answer of cost effectiveness and efficacy for women, while in both arms of the study, the uterus is preserved.

Uterine artery embolisation certainly is a technical major step forward in the prevention of hysterectomy for many patients with symptomatic fibroids.

The next studies on uterine artery embolisation should compare this treatment with other uterus-preserving methods. In case of failure, hysterectomy will not only be the final but also a definitive option.

**Sjoerd de Blok, Amsterdam**

### **We should have open ears and eyes for robotic-assisted laparoscopy**

Magrina JF, Kho RM, Weaver AL, Montero RP, Magtibay PM.

Robotic radical hysterectomy: comparison with laparoscopy and laparotomy. *Gynecol Oncol.* 2008;109:86–91.

*Objective:* Comparison of perioperative results of patients undergoing radical hysterectomy by robotics, laparoscopy, and laparotomy.

*Study design:* Prospective analysis of 27 patients undergoing robotic radical hysterectomy between April 2003 and September 2006. Comparison was made with patients operated by laparoscopy and laparotomy matched by age, body mass index, site and type of malignancy, International Federation of Gynecology and Obstetrics staging, and type of radical hysterectomy.

*Results:* The mean operating times for patients undergoing robotic, laparoscopy, and laparotomy radical hysterectomy were 189.6, 220.4, and 166.8 min, respectively; the mean blood loss was 133.1, 208.4, and 443.6 ml, respectively; the mean rate of blood loss was 0.7, 0.9, and 2.6 ml/min, respectively; the mean number of removed lymph nodes was 25.9, 25.9, and 27.7, respectively; and the mean length of hospital stay was 1.7, 2.4, and 3.6 days, respectively. There were no significant differences in intra- or postoperative complications among the three groups, no fistula formation in any patient, and no conversions in the robotic or laparoscopic groups. At a mean follow-up of 31.1 months, none of the patients with cervical cancer has experienced recurrence.

*Conclusion:* Laparoscopy and robotics are preferable to laparotomy for patients requiring radical hysterectomy.

Operating times for robotics and laparotomy were similar and significantly shorter as compared to laparoscopy. Blood loss, rate of blood loss, and length of hospital stay were similar for laparoscopy and robotics and significantly reduced as compared to laparotomy.

### *COMMENTARY*

Javier F. Magrina and colleagues give supportive proof that laparoscopic and robotic-assisted laparoscopic surgery in gynecologic oncology is as effective as conventional laparotomy. It is not a double-blind randomized study but a clean comparison of perioperative data of patients with the correct oncological criteria who underwent laparoscopic and robotic-assisted laparoscopy compared to laparotomy. This article recommends all gynecological colleagues who have the opportunity and the knowledge to apply laparoscopic and robotic surgery in gynecological oncology to do so. It even points out that robotic laparoscopic surgery is easier to learn than conventional laparoscopic surgery, and the results of the surgery are challenging. My own surgical experience with the “Da Vinci robot” has been proven in every surgical procedure to be more advantageous than conventional laparoscopy. The costs and the time invested for the procedure are to be discussed on another level, but the outcome is definitely better for the patient. The article is of extreme importance because it gives support to gynecological oncologists to perform laparoscopic and robotic-assisted laparoscopy even in the most conservative setup. The article is exceptional. It gives honest data on 27 patients who underwent robotic surgery, 31 patients who underwent laparoscopic radical surgery, and 35 patients who underwent laparotomy radical surgery.

The study is not a double-blind randomized study. That may be a weakness. On the other hand, the surgical experience described in the article, leading to the identical surgical outcome for patients, speaks for the application of laparoscopic and robotic surgery. At present, there are only a few centers that are able to perform robotic surgery; however, the procedure is representative of the possibilities now available and should be recognized. The paper refers to publications on laparoscopic oncologic surgery performed over the last 20 years by Daniel Dargent, Dennis Querleu, Joel Childers, Achim Schneider, Marc Possover, Shailesh Puntambekar, Camran, Farr and Ceana Nezhat as well as by colleagues using surgical robots, such as Diaz-Arrastia et al. 2002, Nezhat et al. 2006, and Reynolds and Advicola 2006.

The article definitely gives laparoscopic surgery and robotic laparoscopic surgery a chance. Robotic laparoscopic surgery allows the surgeon to work in a three-dimensional field, from a sitting position and to plan the surgery exactly. At the present time, this is only possible with the “Da Vinci

robot,” but many trials are underway to implement the use of robotics further into the field of laparoscopy.

I do think we should have open ears and eyes for laparoscopic and robotic-assisted laparoscopic surgery in gynecological oncology, as these techniques represent an accepted surgical alternative in the treatment of cancer.

**Liselotte Mettler, Kiel**

### **Shoulder pain can be resolved by harmless intervention**

Phelps P, Cakmakkaya OS, Apfel CC, Radke OC.

A simple clinical maneuver to reduce laparoscopy-induced shoulder pain: a randomized controlled trial. *Obstet Gynecol.* 2008;111:1155–60.

*Objective:* To estimate the efficacy of a simple clinical maneuver that facilitates removal of residual abdominal carbon dioxide (CO<sub>2</sub>) after laparoscopic surgery to reduce shoulder pain.

*Study design:* A total of 116 female outpatients who were scheduled for elective gynecologic laparoscopic surgery were randomly allocated to either the current standard (control group) or to additional efforts to remove residual CO<sub>2</sub> at the end of surgery. In the control group, CO<sub>2</sub> was removed by passive deflation of the abdominal cavity through the cannula. In the intervention group, CO<sub>2</sub> was removed by means of Trendelenburg position (30°) and a pulmonary recruitment maneuver consisting of five manual inflations of the lung. Postoperative shoulder pain was assessed before discharge and 12, 24, 36, and 48 h later using a visual analog scale (VAS, 0–100). In addition, positional characteristics of the shoulder pain and incidence of post-discharge nausea and vomiting were recorded until 48 h after discharge.

*Results:* Pain scores in the control and intervention groups were 30.3±4.5 compared with 15.6±3.0, 25.7±4.7 compared with 10.8±2.4, and 21.7±4.3 compared with 9.1±2.5 at 12, 24 and 36 h after discharge, respectively (all  $P < 0.05$ ). The intervention reduced positional pain from 63% to 31% ( $P < 0.05$ ) and the incidence of postoperative nausea and vomiting from 56.5% to 20.4% ( $P < 0.001$ ).

*Conclusion:* This simple clinical maneuver at the end of surgery reduced shoulder pain as well as postoperative nausea and vomiting after laparoscopic surgery by more than half.

### **COMMENTARY**

The article ‘A simple clinical maneuver to reduce laparoscopy-induced shoulder pain; a randomized controlled trial’ by Paul Phelps et al. is based on a well-designed and well-conducted study.

To test a hypothesis on reduction of shoulder pain after laparoscopy, patients with gynecological complaints undergoing a laparoscopy were randomly divided in two groups: In the first group, the CO<sub>2</sub> is evacuated at the end of surgery in the usual way (compression of the abdominal wall); in the second group, the anesthesiologist inflates the lungs five times manually in order to promote desufflation by increasing the abdominal pressure. In the last group, less patients experienced shoulder pain (63%) compared to the control group (83%;  $P < 0.05$ ). There was, up to 48 h, a significant difference between both groups in shoulder pain scored on a visual analogue scale (0–100), which was most pronounced 12 h after discharge from the ambulatory center (30.3±4.5 vs 15.6±3.0).

This is an important study that addresses the period of immediate postoperative recovery.

Elementary is the mechanism of the irritation of the phrenic nerve in the diaphragm that is supposed to be the cause of shoulder pain. Is it a direct mechanical effect of CO<sub>2</sub> on the diaphragm or is there a prolonged effect even after evacuation of the CO<sub>2</sub>, which might be caused by an inflammatory reaction of the peritoneum? In the latter case, forced evacuation of the CO<sub>2</sub> might be of lesser importance. Shoulder pain has been reported up to 7 days, a moment that the CO<sub>2</sub> is already completely absorbed. Strongly suggestive of a direct effect of the CO<sub>2</sub> is the shoulder pain after standing up from supine position, which was described in the current study in 63% of patients with shoulder pain.

As the type of surgery may be of importance in the etiology of shoulder pain—longer operations inducing more CO<sub>2</sub> effect on the peritoneum—a possible bias in the study may be the difference in type of surgery between groups: In the intervention group 48/54 (88%), laparoscopies were diagnostic or tubal sterilizations, while in the control group, this was the case in 34/46 (74%) ( $p = 0.07$ ). It would be interesting to register the operating time and study the correlation with the occurrence of shoulder pain.

Early recovery is actually the feature that distinguishes laparoscopy from laparotomy, and one might wonder why there has been so little interest in relieving shoulder pain in the past 40 years that laparoscopy is standard surgery. This may be partly explained by the fact that most patients after laparoscopy are discharged the same day, and the surgeon is unaware of any mild complaints afterwards. Also in my personal experience, patients rarely utter spontaneously shoulder pain as a complaint the next morning after a major laparoscopic operation. The differences between the intervention and the control group are small, not only smaller than was powered for (80% to 50%), but also the absolute figures of the VAS score are low. Though the VAS score was half the value in the intervention group, the mean scores in the control group did not exceed 30. If, however, shoulder

pain may not be—despite the occurrence of 80%—the most important side effect of laparoscopy, it should nevertheless be resolved now a harmless intervention is available.

**Hans Brölmann, Amsterdam**

### The tension-free vaginal tape has gained popularity

Ward KL, Hilton P; UK and Ireland TVT Trial Group  
Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow-up. *BJOG*. 2008;115:226–33.

*Objective:* To compare the long-term outcomes of tension-free vaginal tape (TVT) and colposuspension as primary treatment for stress incontinence.

*Study design:* Multicentre randomised controlled trial. Women with urodynamically confirmed stress incontinence and who had previously failed to respond to conservative treatment were invited to participate.

*Methods:* Three hundred and forty-four women were randomized, 175 to TVT and 169 to colposuspension. This paper reports the 5-year outcomes. The primary outcome at 5 years was a 1-h perineal pad test; other outcomes included clinical examination, Short Form-36 (SF-36) health status and Bristol Female Lower Urinary Tract Symptoms questionnaires.

*Results:* A negative 1-h pad test was recorded in 58/72 (81%) women in the TVT group and 44/49 (90%) in the colposuspension group ( $P=0.21$ , Fisher's exact test) at 5 years. There was an increase in enterocele and rectocele in the colposuspension group; three late tape complications were seen in the TVT group.

*Conclusion:* This study did not detect a significant difference between TVT and colposuspension for the cure of stress incontinence at 5 years. The effect of both procedures on cure of incontinence and improvement in quality of life is maintained in the long term. Vault and posterior vaginal wall prolapse are seen more commonly after colposuspension. Tape erosion may occur several years after surgery.

#### COMMENTARY

Nowadays, the surgical treatment of stress urinary incontinence (SUI) has reached optimal results arriving up to 90% cure rate. Until a few years ago, the colposuspension (C) was considered the gold standard for the surgical treatment of SUI. More recently, the tension-free vaginal tape (TVT), a mid-urethral sling (MUS), for the miniminvasiveness, the possibility to be performed under local anesthesia, and the easy procedure, has gain great popularity.

This randomized clinical trial compares in the long-term (5 years, f-u) the colposuspension with TVT.

The excellent objective results (81% TVT vs. 90% C) confirm the pivotal role of MUS in the treatment of SUI. The minimum invasiveness and the placement of a synthetic mesh without tension create less anatomical distortion.

**Mauro Cervigni, Rome**

### Too early to conclude that infracoccygeal sacropexy is equivalent to sacrospinous suspension

de Tayrac R, Mathé ML, Bader G, Deffieux X, Fazel A, Fernandez H

Infracoccygeal sacropexy or sacrospinous suspension for uterine or vaginal vault prolapse. *Int J Gynaecol Obstet*. 2008;100:154–9.

*Objective:* The objective of this study was to compare infracoccygeal sacropexy (IS) and sacrospinous suspension (SS) for the treatment of uterine or vault prolapse.

*Study design:* A randomized trial of 49 women assigned to either the IS group using IVS tape ( $n=24$ ) or SS group ( $n=25$ ). Concomitant hysterectomy and repairs were performed as appropriate. Evaluations included prolapse staging using the Pelvic Organ Prolapse Quantification system and validated questionnaires for symptoms (PFDI), quality of life (PFIQ), and sexuality (PISQ-12). The primary outcome measure was postoperative pain.

*Results:* Patients' characteristics were similar in both groups. IS was quicker, easier, and less painful than SS ( $P<0.01$ ). Hemorrhage or hematoma rates were similar. Neither rectal injury nor vaginal erosion occurred. Mean follow-up was 16.8 months. Prolapse cure rates, symptom scores, and quality of life were similar. Postoperative cystocele occurred in 4.8% of women after IS and 25% after SS ( $P=0.05$ ).

*Conclusion:* Infracoccygeal sacropexy is equivalent to sacrospinous suspension, with a decreased rate of postoperative pain and cystocele recurrence.

#### COMMENTARY

This is a prospective randomized controlled study that compares infracoccygeal sacropexy and sacrospinous suspension for the treatment of uterine or vault prolapse. The primary outcome measure was postoperative pain. Secondary outcome measures included duration of procedure, intra- and postoperative morbidity, duration of hospital stay, patient's satisfaction, quality of life, sexual activity, anatomical results, and rate of vaginal or rectal erosions.

The authors conclude that infracoccygeal sacropexy is equivalent to sacrospinous suspension, with a decreased rate of postoperative pain and cystocele recurrence. With a mean follow up of 17 months (range, 1.5–32), it is too early to conclude that the procedures are equivalent. Perhaps, the authors will continue to follow up these women for a longer period.

Our experience has shown that subsequent vaginal vault prolapse after vaginal or abdominal hysterectomy can considerably be reduced by McCall's culdoplasty, and several studies have demonstrated this (1, 2). The McCall culdoplasty does not lead to a disruption of the vaginal axis and gives excellent anatomical and functional results in maintaining support, especially in sexually active patients. Therefore, insertion of a mesh with its associated complications of erosion, extrusion, etc. can be greatly reduced by a simple vault suspension procedure during hysterectomy.

A study comparing 62 patients who underwent sacrospinous ligament fixation and 62 members of a matched-control group who underwent modified McCall culdoplasty during vaginal hysterectomy and reconstructive pelvic surgery found no significant difference in postoperative sexual function but significant increase in operating time, blood loss, recurrent cystocele, and vault prolapse in the sacrospinous ligament fixation arm. They therefore did not recommend sacrospinous ligament fixation as a prophylactic measure at vaginal hysterectomy in patients with uterovaginal prolapse (3).

In patients with vault prolapse, the choice of procedure, i.e., sacrospinous fixation, sacrocolpopexy, or infracoccygeal sacropexy depends on the available evidence, expertise of surgeon, and characteristics of the patient. Although we would recommend this article to surgeons who perform this kind of surgery, unfortunately, the evidence and results do not convince us to change our practice.

In the UK, the National Institute for Clinical Excellence (NICE) has decided that, if a doctor wants to carry out posterior infracoccygeal sacropexy for vaginal vault prolapse, he or she should make sure that the patient under-

stands what is involved and that there are still uncertainties over the safety of the procedure and how well it works (4). The multifilament IVS tape used in the study is no longer recommended owing to an increased risk of erosion and infection. The authors had to stop enrolment before achieving the calculated power due to change in the type of tape. The inability to achieve the adequate recruitment and short follow-up may explain the minimal complication rate of the infracoccygeal sacropexy and equivalent success rate to sacrospinous suspension. The minimal difference in surgical time, bleeding, and difficulty and the marginal increase in postoperative lower urinary tract symptoms are not sufficient enough to warrant recommendation of the procedure without further long-term follow-up.

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**Arasee Renganathan and Linda Cardozo, London**