

Recent literature with comments

© Springer-Verlag 2009

Lymphadenectomy provides important prognostic information

Benedetti Panici P et al.

Systematic pelvic lymphadenectomy vs. no lymphadenectomy in early-stage endometrial carcinoma: randomized clinical trial. J Natl Cancer Inst 2008;100:1707–1716

Background: Pelvic lymph nodes are the most common site of extrauterine tumor spread in early-stage endometrial cancer, but the clinical impact of lymphadenectomy has not been addressed in randomized studies. We conducted a randomized clinical trial to determine whether the addition of pelvic systematic lymphadenectomy to standard hysterectomy with bilateral salpingo-oophorectomy improves overall and disease-free survival.

Methods: From October 1, 1996 through March 31, 2006, 514 eligible patients with preoperative International Federation of Gynecology and Obstetrics stage I endometrial carcinoma were randomly assigned to undergo pelvic systematic lymphadenectomy ($n=264$) or no lymphadenectomy ($n=250$). Patients' clinical data, pathological tumor characteristics, and operative and early postoperative data were recorded at discharge from hospital. Late postoperative complications, adjuvant therapy, and follow-up data were collected 6 months after surgery. Survival was analyzed by use of the log-rank test and a Cox multivariable regression analysis. All statistical tests were two-sided.

Results: The median number of lymph nodes removed was 30 (interquartile range=22–42) in the pelvic systematic lymphadenectomy arm and 0 (interquartile range=0–0) in the no-lymphadenectomy arm ($P<0.001$). Both early and late postoperative complications occurred statistically significantly more frequently in patients who had received pelvic systematic lymphadenectomy (81 patients in the

lymphadenectomy arm and 34 patients in the no-lymphadenectomy arm, $P=0.001$). Pelvic systematic lymphadenectomy improved surgical staging as statistically significantly more patients with lymph node metastases were found in the lymphadenectomy arm than in the no-lymphadenectomy arm (13.3% vs 3.2%, difference=10.1%, 95% confidence interval [CI]=5.3% to 14.9%, $P<0.001$). At a median follow-up of 49 months, 78 events (i.e., recurrence or death) had been observed and 53 patients had died. The unadjusted risks for first event and death were similar between the two arms (hazard ratio [HR] for first event=1.10, 95% CI=0.70 to 1.71, $P=0.68$, and HR for death=1.20, 95% CI=0.70 to 2.07, $P=0.50$). The 5-year disease-free and overall survival rates in an intention-to-treat analysis were similar between arms (81.0% and 85.9% in the lymphadenectomy arm and 81.7% and 90.0% in the no-lymphadenectomy arm, respectively).

Conclusion: Although systematic pelvic lymphadenectomy statistically significantly improved surgical staging, it did not improve disease-free or overall survival.

COMMENTARY

Endometrial cancer is the most common gynecologic malignancy and due to an aging population and an increase in obesity the incidence of endometrial cancer might increase in the future. However, there is no consensus about the standard of care in endometrial cancer.

The most common site for the spread of early-stage endometrial cancer is the pelvic lymph nodes. Although several authors have suggested that complete lymphadenectomy may be associated with improved survival outcomes, the results of most of these studies have been equivocal because they were retrospective analysis and did not include control groups.

In this randomized clinical trial, Panici PB et al. showed that systematic pelvic lymphadenectomy did not improve disease-free or overall survival. The median number of lymph nodes removed was 30 (interquartile range=22–42) in the pelvic systemic lymphadenectomy arm which demonstrates that those patients were surgically correctly staged.

Although systematic pelvic lymphadenectomy was associated with statistically significantly longer median operating time than no lymphadenectomy (180 vs 120 min, $P<0.001$), median estimated blood loss and the rate of patients undergoing a blood transfusion were similar in the two arms.

It was not surprising to see that both early and late postoperative complications occurred statistically significantly more frequently in patients who had received pelvic systemic lymphadenectomy. Most of the difference in morbidity was due to lymphocysts and lymphedema that occurred in 35 patients in the lymphadenectomy arm and four patients in the no lymphadenectomy arm.

After a median follow-up of 4 years, there was no difference in patient outcomes between the two arms. Thirty-four (12.9%) of the 264 patients in the lymphadenectomy arm and 33 (13.2%) of the 250 patients in the control arm had disease recurrence. The median time to disease recurrence was 14 months in the lymphadenectomy arm and 13 months in the control arm. Overall 5-year survival estimates were similar in both groups: 86% for the lymphadenectomy arm and 90% for the non-lymphadenectomy.

These results are consistent with the recently published results of the ASTEC study group [1]. Eighty five centers in four countries randomly allocated 1,408 women with early stage endometrial carcinoma to standard surgery (hysterectomy and BSO, peritoneal washings, and palpation of para-aortic nodes; $n=704$) or standard surgery plus lymphadenectomy ($n=704$). Similar to the results published by Panici PB et al., the ASTEC study group showed no evidence of benefit in terms of overall or recurrence-free survival for pelvic lymphadenectomy in women with early endometrial cancer. However, in the contrary to the study published by Panici PB et al., only 40% of the patients of the lymphadenectomy group had >14 lymph nodes harvested at the time of surgery. Therefore, the surgical staging was clearly insufficient in the ASTEC study.

Although Panici PB et al. demonstrated that pelvic lymphadenectomy did not improve disease-free or overall survival, it clearly showed that surgical staging of the disease was improved with the systematic use of lymphadenectomy. A total of 13.3% of the women in the lymphadenectomy arm were found to have disease spread to pelvic lymph nodes, compared with 3.2% of the women in the control arm (macroscopically enlarged lymph nodes

where excised at the time of surgery). Disease spread to the nodes was associated with poorer survival. Therefore, this trial supports the notion that lymphadenectomy provides important prognostic information and helps guide adjuvant treatment recommendations.

Reference

1. Efficacy of systematic pelvic lymphadenectomy in endometrial cancer (MRC ASTEC trial): a randomised study from the ASTEC study group. *Lancet* (2009) 373:125–136

Michael D. Mueller, Bern, Switzerland

We need more high-quality studies

Thakar R, Chawla S, Scheer I, Barrett G, Sultana AH
Sexual function following pelvic floor surgery. *Int J Gynecol Obstet* 2008;102:110–114

Objective: The objectives of the study were to prospectively evaluate sexual function in women who underwent surgery for incontinence and/or prolapse using the Pelvic Organ Prolapse–Urinary Incontinence Sexual Questionnaire (PISQ) and to provide a preliminary evaluation of the PISQ's psychometric properties for a population of women in the UK.

Methods: Women who underwent surgery for pelvic organ prolapse and/or urinary incontinence completed the PISQ, the Sheffield Prolapse Symptoms Questionnaire, and the King's Health Questionnaire preoperatively and 4 months postoperatively. Rates of item completion were assessed to evaluate the performance of the PISQ, and Cronbach's alpha values and item-total correlations were calculated for the full scale and each of the three domains (behavioral-emotive, physical, and partner-related).

Results: Thirty-five women responded to the questionnaire. Postoperatively, an improvement was demonstrated for overall score ($P=0.002$) and for physical ($P=0.001$) and partner-related domains ($P=0.004$).

Conclusion: Women reported a significant improvement in sexual function 4 months after surgery for incontinence and prolapse.

COMMENTARY

The paper by Thakar et al. deals with a matter of great interest and controversy as is sexual function after surgery for stress urinary incontinence and/or genital prolapse.

Pelvic floor disorders, such as stress urinary incontinence or genital prolapse, are very common and, at least, one of four women with genital prolapse or stress

incontinence report impaired sexual function due to the condition and significantly lower quality-of-life scores.

Sexual arousal results in congestion and vaginal wall thickening, tenting, and lubrication as well as production of mucous secretion and opening of the vaginal orifice. Clearly, all these functions might be disturbed as a result of vaginal surgery, but remarkably few studies have addressed these issues and results from studies differ. Differences in the methodologies used to evaluate sexuality among patients who had undertaken surgical repair of pelvic floor disorders are likely to explain these differences among studies.

Thakar et al. prospectively evaluated sexual function in a group of woman before and after surgery for incontinence and/or genital prolapse using the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire (PISQ), a questionnaire non-validated in Britain.

The main conclusion from this paper is that surgery significantly improves sexual function when evaluated 4 months after surgery as reflected by a significant change from the preoperative score.

The strength of this study is that it has been done prospectively using a disease-specific measure to evaluate the sexual function. However, the PISQ has not been validated for use in the UK raising doubts about its validity in that population as suggested by the high rate of missing data in some questions and the low value of the Cronbach's alpha in some domains of the PISQ.

This study has also other limitations. First, the number of women included was low (46 women) and just 75% of patients included answer after 4 months, thus leaving only 35 patients available for analysis. Second, the surgical treatment performed included 11 different interventions as diverse as tension-free vaginal tape and sacrocolpexy, limiting the validity of the conclusions reached by the authors. Third, the follow-up period was short (just 4 months) and no objective evaluation such as vaginal examination and/or urodynamic studies at the time of follow-up were performed. Finally, the degree of distress related to sexual dysfunction is not evaluated by the PISQ; therefore, this study does not permit to draw any conclusion about the effect of surgery for pelvic floor disorders on sexual dysfunction as a whole.

In summary, the paper by Thakar et al. adds some information on a controversial matter but, in order to draw definite conclusions, we need more high-quality studies focusing on postoperative vaginal changes and its relationship with changes in sexual activity and satisfaction, taking into account that a lot of individual physical and psychological parameters (i.e., self/body image, sexual desire, partner related factors, ...) may influence the results.

Francisco Carmona, Barcelona, Spain

It is a 'must read' article

Possover M

Laparoscopic management of neural pelvic pain in women secondary to pelvic surgery. Fertil Steril 2008; online

Objective: The aim of this study was to report the impact of the laparoscopic approach to the pelvic nerves in the management of neural pelvic pain in women secondary to pelvic surgery.

Methods: One hundred twenty consecutive patients with pelvic neural pain after failure of all previous surgical and medical treatments were the subjects of the study. Control of visceral pelvic pain was based on the laparoscopic implantation of neuroprosthesis procedure to the superior hypogastric plexus for permanent neuromodulation while pelvic somatic pain was primarily managed by laparoscopic nerve decompression. Comparison pre- and postoperatively of the pain situation with the visual analogue scale (VAS score) and consumption of analgesics was conducted.

Results: Significant improvement was obtained in 65.5% of the patients with pelvic somatic pain ($n=113$), whereas in seven patients with visceral pelvic pain, four of them reported on a significant reduction in the symptoms after neuromodulation of the superior hypogastric plexus.

Conclusions: Laparoscopy is a unique method for diagnosis and therapeutic management of surgically damaged nerves and must be considered as a first-line option in the treatment of pelvic somatic pain, whereas in regard to the management of pelvic visceral pain, medical treatment remains the first-line treatment.

COMMENTARY

The article studies the following:

Population: women with pelvic pain secondary to pelvic surgery

Intervention: laparoscopic implantation of neuroprosthesis (LION) for visceral pelvic pain and laparoscopic neurolysis for somatic neural pelvic pain

Outcome: improvement in pain scores measured objectively with the visual analogue scale (VAS) and consumption of analgesics

Design of study: prospective

The article's results are encouraging with 5/7 patients in the LION group reporting a reduction of pain of 5 or more points on the visual analogue scale. In the simple laparoscopic neurolysis for somatic pain ($n=101$), the author has not given the exact reduction in pain scores on VAS but has reported on subjective improvement in pain in 66 patients. The current evidence on effectiveness of laparoscopic uterine nerve ablation is that it is not effective

in relieving CPP and hence should not be used¹. However, these studies do not specifically consider the subgroup of patients that are studied here.

In my view, it is a ‘must read’ article. The intervention is rather new and so is the method of dealing with the problem. The author has included appropriate background and the style of writing is academic and clear.

Strengths of the study are its prospective design, complete follow-up, and objectively measured outcomes and conclusions which flow from the study’s findings.

The limitations are that it is not a randomized controlled trial (RCT) and the follow-up period is variable between 1 and 37 months.

The study provides body of evidence (level II a) on effectiveness of LION and laparoscopic neurolysis in a subgroup of patients with neural pelvic pain after pelvic surgery where other treatment options have been exhausted. Longer term follow-up is not available; hence, this cannot be reliably commented upon. The results will be helpful in setting up a robust RCT with a long-term follow-up. It will also be useful to perform cost-effectiveness analysis of this new intervention in the future.

The implications for clinical practice are that gynecologists should develop a more in-depth understanding of neurofunctional anatomy of pelvic nerves in order to classify neural pelvic pain better. Surgical expertise should be developed to treat such patients at the time of laparoscopy, provided the long-term results are good. Patients with somatic pelvic pain should be offered laparoscopy sooner rather than later to avoid “memorization” of pain. In the interim, the gynecologists should either recruit these difficult-to-treat patients to RCT, or if they perform such procedures, it is recommendable to collect the outcome data prospectively. In conclusion, this article discusses a new finding with a technical advance.

Pallavi M. Latthe, Birmingham, UK

Hysteroscopy and MRI are both useful for staging and planning the correct surgical strategy

Cicinelli E, Marinaccio M, Barba B, Tinelli R, Colafoglio G, Pedote P, Rossi C, Pinto V

Reliability of diagnostic fluid hysteroscopy in the assessment of cervical invasion by endometrial carcinoma: a comparative study with transvaginal sonography and MRI. Gynecol Oncol 2008; 111: 55–61

Objective: This study aimed at comparing the reliability of diagnostic fluid hysteroscopy, transvaginal sonography (TVS), and magnetic resonance imaging (MRI) to assess

pre-operatively the presence of cervical involvement by endometrial carcinoma.

Methods: Cervical involvement was assessed by diagnostic fluid mini-hysteroscopy, TVS, and MRI before surgery in 100 patients with histological diagnosis of endometrial carcinoma. Results were compared with pathological examination on surgical specimen. The sensitivity, the specificity, the positive and negative predictive values, the accuracy, and the positive and negative likelihood ratios (LR) of the three techniques for recognizing the cervical involvement by the carcinoma were calculated.

Results: At histology, cervical involvement was found in 15 cases. Compared to TVS and MRI, hysteroscopy showed the highest sensitivity (0.53, 0.67, and 0.93, respectively). The specificity of MRI was significantly higher than both hysteroscopy and TVS (0.95, 0.88, and 0.82, respectively). The diagnostic accuracy of hysteroscopy (0.89) and MRI (0.91) was similar and significantly higher than TVS (0.78). The LR for a positive result of MRI was 14.16, which was 2.08 and 4.68 times higher than that of hysteroscopy and TVS, respectively.

Conclusions: In conclusion, this study demonstrates that in women with endometrial carcinoma the exclusion of cervical canal involvement at hysteroscopy is more reliable than at MRI and TVS while MRI is the most reliable technique for predicting cervical involvement. In the pre-surgical work-up of patients affected by endometrial carcinoma, hysteroscopy and MRI are both useful for staging and planning the correct surgical strategy.

COMMENTARY

This study compared the performance of diagnostic fluid hysteroscopy, transvaginal sonography (TVS), and magnetic resonance imaging (MRI) to assess pre-operatively the presence of cervical involvement in 100 patients with endometrial carcinoma. Hysteroscopy showed the highest sensitivity (0.93), whereas MRI had the highest specificity (0.95). The authors concluded that in women with endometrial carcinoma hysteroscopy is the most reliable for the exclusion of cervical involvement and that MRI is the most reliable technique for predicting cervical involvement. Therefore, they advocate the use of both hysteroscopy and MRI for pre-operative staging.

A limitation of this study is the absence of an assessment of costs and side effects of the different techniques. Moreover, this study is limited to the assessment of cervical involvement and this is only one small part of the pre-operative staging procedures in patients with endometrial cancer. Recently, we published a review on endometrial cancer in the *Lancet* (Amant et al. 2005). We concluded that the sensitivity to detect retroperitoneal lymph nodes is

better for computed tomography (CT) than for MRI. TVS is simple and readily available and has reasonable accuracy in predicting cervical and myometrial invasion from endometrial cancer. A logistic regression model based on TVS and several variables was as accurate as most other proposed methods for measuring depth of myometrial invasion (De Smet et al. 2006). It was almost as accurate as contrast-enhanced MRI, which is currently seen as the best method for myometrial assessment. However, MRI is costly, is not so widely available, can induce contrast allergies, and is not appropriate for all patients (e.g., those who are extremely obese or who have claustrophobia).

A final concern about the present study is the risk of spilling of malignant cells that may occur with fluid hysteroscopy in patients with endometrial carcinoma. A study on 222 patients with endometrial carcinoma reported significantly more positive peritoneal cytology after fluid hysteroscopy (Zerbe et al. 2000). At present, we still need proper long-term studies to assess whether there might be any effect of spilling on patient survival.

I would rate this article as interesting and recommendable reading, but this article is not likely to change current clinical practice. It is not feasible to perform TVS and diagnostic fluid hysteroscopy and CT scan, and MRI next to other diagnostic staging techniques such as chest X-ray in all patients presenting with endometrial cancer. Clinicians need to critically look at all available diagnostic techniques and apply them in an individual patient when their use is appropriate and only if the result of the diagnostic technique might change the management of the patient. For example, if distant metastases are visualized, the knowledge about possible cervical involvement is not very important, and in patients without metastases, but with deep myometrial invasion, most gynecological oncologists will perform a lymphadenectomy irrespective of the status of cervical involvement.

In conclusion, this article raises a controversial issue, and more studies of costs, benefits, and risks are needed before office hysteroscopy could be routinely applied preoperatively in patients presenting with endometrial cancer.

References

- Amant F, Moerman Ph, Neven P, Timmerman D, Van Limbergen E, Vergote I. Endometrial cancer: review. *Lancet* 2005; 366:491–505
- De Smet F, De Brabanter J, Van den Bosch T, Pochet N, Amant F, Van Holsbeke C, Moerman P, De Moor B, Vergote I, Timmerman D. New models to predict depth of infiltration in endometrial carcinoma based on transvaginal sonography. *Ultrasound Obstet Gynecol* 2006; 27:664–671
- Zerbe MJ, Zhang J, Bristow RE, Grumbine FC, Abularach S, Montz FJ. Retrograde seeding of malignant

cells during hysteroscopy in presumed early endometrial cancer. *Gynecol Oncol* 2000; 79:55–58

Dirk Timmerman, Leuven, Belgium

Transvaginal approach for upper gastrointestinal tract and transgastric approach for pelvic procedures

Bergman S, Melvin WS

Natural orifice transluminal endoscopic surgery. *Surg Clin North Am* 2008;88:1131–1148

This article provides an overview of the currently available animal data on natural orifice transluminal endoscopic surgery (NOTES) on the topics of transluminal access and closure, iatrogenic intraperitoneal complications, especially infection and overinsufflation, spatial orientation, and the development of enabling technologies. Human trials to date are also reviewed and discussed.

COMMENTARY

This article provides an overview and state of the art about NOTES surgery in general. It reviews 94 articles among 122 publications till now.

As we think, with the available data, NOTES is a revolution in minimal invasive surgery.

We do not know if it will be the evolution after laparoscopy and robotics. This article concludes with the same idea.

More advances are done in NOTES surgery, especially in the retroperitoneum. We describe extraperitoneal lymphadenectomy in porcine model where this procedure is demonstrated feasible and safe (1). Other procedures (adrenalectomy, nephrectomy, ...) are also done in our institution and can be found on www.websurg.com.

This article would be rated as ‘must read’. However, many points have to be discussed. Acceptability studies among patients are still rare for the moment (2). An important question to answer would be patients’ acceptability to use the transvaginal approach to have nongynecological procedures (i.e., cholecystectomy) and vice versa. When it comes to gynecologists’ acceptability about transvaginal route, only 28.8% would recommend NOTES to their patients if NOTES presented the same surgical risks as the laparoscopic approach (3). When it comes to terminology, we would like to add that single port surgery could be considered a fetal NOTES surgery. For genitourinary approach, the authors did not discuss the retroflexion issue when performing procedures in the pelvis, as they did for the gastric approach. According to our experience, one could overcome this problem by the surgeon’s position on the left side of the patient. For the

moment, we think that vaginal route is the easiest to do and to close. Data about transvaginal procedures are more and more published. Also, as upper gastrointestinal tract procedures were the first procedures to be done by NOTES, transvaginal approach would give better exposure and working position avoiding retroflexion, as would do transgastric approach for pelvic procedures.

For the moment, we do not have consistent data to recommend any change or elaborate indications for NOTES surgery.

We classify this article as a technical advancement.

References

- 1 - Nassif J, et al. Transvaginal extraperitoneal lymphadenectomy by natural orifices transluminal endoscopic surgery (NOTES) technique in porcine model: feasibility and survival study, *Gynecol Oncol* (2008) doi:10.1016/j.ygyno.2008.09.038 (in press)
- 2 - Varadarajulu S, Tamhane A, Drelichman ER. Patient perception of natural orifice transluminal endoscopic surgery as a technique for cholecystectomy. *Gastrointest Endosc*. 2008 May; 67(6):854–860 Epub 2008 Mar 20.
- 3 - Thele F, Zygmunt M, Glitsch A, Heidecke CD, Schreiber A. How do gynecologists feel about transvaginal NOTES surgery? *Endoscopy*. 2008 Jul;40(7):576–580

Joseph Nassif, Strasbourg, France

A choice should be offered to the woman

Gorlero F, Lijoi D, Biamonti M, Lorenzi P, Pullè A, Dellacasa I, Ragni N

Hysterectomy and women satisfaction: total versus subtotal technique. *Arch Gynecol Obstet* 2008;278: 405–410

Objective: The impact of different surgical procedures on women's satisfaction after hysterectomy is a topical issue. The aim of this study was to investigate the impact of subtotal and total hysterectomy on women's satisfaction, evaluated with questionnaire assessment of sexual activity, body image, and health status.

Methods: A prospective, randomized, non-blind study was conducted. In the study period of 3 years, 105 women were enrolled and completed the questionnaires [EuroQol (EQ-5D), body image scale (BIS), sexual activity questionnaire] 2 weeks before and 1 year after surgery.

Results: Both total and sub-total hysterectomy resulted with improvements in the women's sexual satisfaction (1 year

after surgery), but no statistically significant differences were reached between the two groups. A highly significant difference ($P < 0.001$) in the perception of the body image between total and sub-total hysterectomy, at 1 year after surgery, was underlined. The health-related quality of life resulted significantly better in the “sub-total hysterectomy” group 1 year after surgery ($P < 0.05$).

Conclusion: Considering these results, why should a total hysterectomy be performed, if the women's satisfaction seems to be higher using the sub-total technique? In our opinion, the woman undergoing hysterectomy for benign conditions must be counseled regarding the differences between the two techniques and, when possible, a choice must be offered to the woman.

COMMENTARY

The article describes a prospective, randomized, non-blind study comparing total (TH) and subtotal hysterectomy (STH) by laparotomy. After randomization in comparable groups, 117 women were operated by the same surgeon; 89.7% were saved to follow-up after 1 year. By means of validated (EuroQol, BIS, SAQ) questionnaires, the authors evaluated perioperative complications and influences on sexual activity, body image, and health status. No statistical differences were found except for the positive influence of the subtotal hysterectomy on the women's body image.

This recommended article demonstrates no statistical differences concerning perioperative complications, health status, and sexual behavior. Several studies quoted in the article show also no differences in postoperative urinary incontinence or lesion of neuroanatomical structures but a higher rate of cervical carcinoma (0.1–0.3%) and bleeding after STH.

The most important positive key end point here was the influence on the body image (body image scale, BIS). The authors speculate the significantly ($P < 0.001$, SPSS, chi-square) fewer problems with the body image related to the patients consciousness of still having the cervix after operation. They conclude that, as neither procedure has proven to be surgically superior, a choice should be offered to the women considering their desires but also explaining the potential consequences of their decisions.

This work again stresses the importance of investigating and counseling the women before hysterectomy, not only to define the optimal individual surgical therapy, but also to consider possible long lasting benefits on the health-related quality of life.

Garri Tchatchian and Rudy Leon De Wilde
Oldenburg, Germany

The pre-conceptual use of MRgFUS has to be further evaluated

Fukunishi H, Funaki K, Sawada K, Yamaguchi K, Maeda T, Kaji Y

Early results of magnetic resonance-guided focused ultrasound surgery of adenomyosis: analysis of 20 cases. *J Minim Invasive Gynecol* 2008;15:571–579

Objective: The aims of the study were to evaluate the thermal ablative effects of magnetic resonance-(MR) guided focused ultrasound surgery (MRgFUS) on adenomyosis and to assess improvement in clinical parameters.

Methods: Twenty patients with adenomyosis were treated with MRgFUS. Extensive adenomyosis (six cases) was treated with two applications. Uterine volume was evaluated by MR imaging before and immediately after MRgFUS. Ablation of adenomyosis and the architecture of non-perfused areas were evaluated immediately after MRgFUS. Improvement in patient symptoms was assessed through the symptom severity score questionnaire (Canadian Task Force Classification II-3).

Results: We classified the nonperfused lesions on contrast-enhanced MR images immediately after MRgFUS into three types: lesions with round margins (type R), serrated margins (type S), and honeycomb architecture (type H). Type R was the most common (16/20 patients). Most adenomyosis lesions could be sufficiently ablated close to the serosal surface or to the endometrium by MRgFUS. The mean uterine volume 6 months after therapy was decreased by 12.7%. Symptom severity score improved significantly during 6 months of follow-up. No serious complications were observed.

Conclusions: These early results indicate the safe and effective ablation of adenomyosis tissue by MRgFUS. The procedure also resulted in the improvement in clinical symptoms during 6 months of follow-up.

COMMENTARY

Hidenobu Fukunishi and co-workers report that magnetic resonance-guided focused ultrasound surgery (MRgFUS) is effective in reducing symptoms of adenomyosis during 6 months of follow-up. This is the first case series report

as well as the second paper on using MRgFUS as a thermal ablation treatment in women with symptomatic adenomyosis. It is a prospective, single arm study which provides information on the MRgFUS procedure and its effects on symptom severity scores as well as on uterine volumes in a rather small group of 20 patients.

In the enrolment of the patients, the authors used established criteria for adenomyosis on MRI. Unfortunately, they included also ten patients with (multiple) intramural and/or subserosal uterine myoma as well. This endangers the homogeneity of the study group as recently several studies pointed out that it becomes difficult to distinguish myoma from adenomyosis if more than three myomas are found and/or a uterine volume of $<400\text{ cm}^3$ is measured. As the mean pretreatment uterine volume in this series is 445 cm^3 (and no data are shown on mean number and size of the myoma), one may wonder whether in the ten patients with uterine myoma the diagnosis of adenomyosis could be clearly established. Moreover, these diagnostic doubts may be extrapolated towards the results of the MRgFUS treatment raising the question which entity (myoma or adenomyosis) has been actually treated in 50% of the cases. In my opinion, this issue is not resolved by providing separate analyses of the symptom severity scores in patients with adenomyosis alone and for those with both adenomyosis and myoma which show pretty much the same improvement in both groups after MRgFUS treatment.

In this study, older patients (mean age 42.5 ± 3.9 years) with no plans for childbearing, were included. MRgFUS improved their symptoms and may have formed an alternative to hysterectomy. This study shows also that MRgFUS is a safe and feasible treatment. On the other hand, no data are provided on cost efficiency which is relevant when considering the high costs for equipment and treatment time (up to 240 min from first to last sonication).

Firm conclusions cannot be drawn yet and more studies are needed to ascertain the efficacy and safety of MRgFUS as a new treatment for adenomyosis. Especially in younger women, the pre-conceptual use of MRgFUS has to be further evaluated.

Velja Mijatovic, Amsterdam, Netherlands