Weigh Advantages of UAE Vs. Failure Rate, Extra Risk

BY MARY ANN MOON
Contributing Writer

The choice between standard surgery to remove uterine fibroids and uterine artery embolization comes down to weighing the benefits and risks of the two procedures, because quality of life and other outcomes at 1 year are fairly comparable, according to Dr. Richard D. Edwards and his associates in the Randomized Trial of Embolization versus Surgical Treatment.

The advantages of uterine artery embolization (UAE)—significantly shorter hospital stay, less postprocedure pain, and faster return to usual activities—must be weighed against a treatment failure rate that may be as high as 20% and a small but still significantly increased risk of late adverse events, the researchers said.

Of the women in the uterine artery embolization group, 34% developed minor complications, compared with 20% of those in the standard surgery group.

"The results of our study make clear that the choice between surgery and uterine artery embolization for symptomatic uterine fibroids involves [tradeoffs]," said Dr. Edwards of Gartnavel General Hospital, Glasgow, Scotland, and his associates.

The trial, specifically designed to assess quality of life and other outcomes at 1 year of follow-up, involved 140 women with one or more fibroids larger than 2 cm who were treated at 27 hospitals throughout the United Kingdom. Approximately twice as many subjects were randomly assigned to the UAE group as to the surgical group, to allow better characterization of outcomes of the embolization and minimal reduction in statistical power.

Quality of life—the primary outcome measure—was assessed using the Medical Outcomes Study's 36-item short-form general health survey (MOS SF-36). There were no significant differences between the two groups at 1 year on any of the eight components measured, the investigators said (N. Engl. J. Med. 2007; 356:360-70).

Of the UAE group, 21 women (20%) required an additional invasive procedure—hysterectomy or repeat UAE—for continued or recurrent symptoms. Ten of them had the second intervention within 1 year and 11 had it within 2 years of the initial procedure. In contrast, symptom scores were significantly better in the surgery group at all time points assessed.

Women in the UAE group had significantly shorter hospital stays (1 day vs. 5 days), resumed their usual activities much sooner, and reported significantly less pain and better social function post procedure.

A similarly high percentage of women in both groups (93% of the surgical group and 88% of the UAE group) said they would recommend their procedure to a friend.

Rates of major adverse events and of minor complications did not differ significantly, but the timing and nature of these events did.

There were 16 major adverse events (15%) in the UAE group and 10 (20%) in the surgery group, results which did not differ significantly.

However, 15 of the 16 such events occurred after hospital discharge in the UAE group, whereas only one such event occurred after hospital discharge in the surgery group.

A total of 36 women in the UAE group (34%) developed minor complications, usually the pyrexia, pain, and elevated markers of inflammation of postembolization syndrome. Similarly, 10 women in the surgery group (20%) developed minor complications, usually infection.

Embolization was the more cost effective of the two procedures overall, even though it required more imaging studies in the year following the intervention and also required more secondary interventions after treatment failure, Dr. Edwards and his associates reported.

This study was supported in part by three companies that manufacture embolic agents: William Cook Europe, Cordis Corp., and Biocompatibles Ltd. ■

Laparoscopic Occlusion May Offer Better Pregnancy Outcomes

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

Orlando — Laparoscopic uterine artery occlusion is an effective way to manage patients with symptomatic fibroids, and may offer better outcomes than uterine artery embolization for women desiring pregnancy after the surgery, Dr. Zdenek Holub said at a meeting on laparoscopy and minimally invasive surgery.

'Our miscarriage rate was significantly lower than the rate we see associated with uterine artery embolization in the literature.'

In a prospective follow-up study, Dr. Holub found only a 9% miscarriage rate among women who became pregnant after the procedure.

That compares very favorably with the 14% rate he and his colleagues found in a previous study they performed of uterine artery embolization for symptomatic fibroids, he said.

The laparoscopic occlusion study included 161 women (mean age 37 years). All of them had one to three symptomatic fibroids with a mean size of 6 cm. The mean follow-up time was 34 months, with postoperative visits at 3, 6, and 12 months, followed by yearly visits.

The mean operative time was 35 minutes, and patients had minimal blood loss, said Dr. Holub, chairman of obstetrics and gynecology at the Baby Friendly Hospital in Kladno, Czech Republic.

Postoperative complications occurred in 11 patients, and included port-site bleeding, hemorrhage, fever, and fibroid necrosis. There were no life-threatening complications.

At 12 months' follow-up, the mean reduction in fibroid volume was 56%, with the size of the dominant fibroid reduced by a mean of 72%. At 34 months, 87% of the group was without fibroid recurrence.

Sixty-three patients desired pregnancy after their surgery. A total of 32 pregnancies occurred; 29 women conceived naturally. There were three miscarriages (9%).

The preterm delivery rate was 10%, and 50% of the babies were delivered by cesarean section

"Our miscarriage rate was significantly lower than the rate we see associated with uterine artery embolization in the literature," said Dr. Holub at the meeting sponsored by the Society of Laparoendoscopic Surgeons. "In a control group of women who got embolization at our hospital, we had a 14% miscarriage rate."

A more detailed account of the study has been published (Int. J. Gynaecol. Obstet. 2007;1:44-5). ■

Clonidine With Local Anesthetic Enhances Peripheral Nerve Block

BY SHERRY BOSCHERT
San Francisco Bureau

Chicago — Adding clonidine to a local anesthetic hastens the onset of a peripheral nerve block, prolongs the nerve block's effects, and reduces postoperative pain, Dr. Ahmad Elsharydah reported in a poster presentation at the annual meeting of the American Society of Anesthesiologists.

His conclusions came from a meta-analysis of data on 601 adults in 16 randomized, controlled studies that compared the addition of either clonidine or placebo to a single injection of local anesthetic for peripheral nerve block.

Dr. Elsharydah and his associates undertook the meta-analysis because previous studies presented conflicting conclusions about the benefits of adding clonidine to local anesthetics in peripheral and central nerve blocks.

Each of the studies in the meta-analysis was reviewed by three investigators.

The studies did not provide enough data to draw a firm conclusion about the safety of combining clonidine with local anesthetic, but most investigators reported minimal or no adverse reactions, said Dr. Elsharydah of the anesthesia and surgery departments at Louisiana State University, Shreveport.

Dr. Elsharydah has no association with the company that makes clonidine.

Most patients in the 16 studies received peripheral nerve blocks in their upper extremities. The most common local anesthetics used were ropivacaine or mepivacaine; from 0.1 to 3.8 mcg/kg of clonidine was added to the anesthetics.

Pain assessed by visual analog scale scores was significantly lower at multiple points in time after surgery in patients who received clonidine. The clonidine group also needed less postoperative morphine, especially in the first 24 hours, he said.

The time from administration of the peripheral nerve block to the onset of effects was shorter in the clonidine group, and the effects of the block lasted significantly longer than in the placebo group.

Nine of the 16 studies found no difference between groups in the odds of developing hypotension, bradycardia, or sedation, although these findings were not published, Dr. Elsharydah said. Meta-analyses showed that clonidine use was associated with an increased risk of sedation in three studies, a higher risk of hypotension in three studies, and greater odds of bradycardia in three studies.

More well-designed, controlled trials are needed to confirm the findings of this meta-analysis, he said. ■