UROGYNECOLOGY

Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up

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OBJECTIVE: The objective of the study was to compare anterior colporrhaphy with and without a mesh.

STUDY DESIGN: Two hundred two women with anterior prolapse were assigned to undergo colporrhaphy alone or reinforced with a tailored polypropylene mesh. Before and 2, 12, 24, and 36 months after surgery, the outcome was assessed by examination and standard questions. The primary endpoint was anatomic recurrence of anterior vaginal prolapse. Secondary outcomes were symptom resolution, reoperation, and mesh exposure.

RESULTS: Recurrences of anterior vaginal prolapse were noted in 40 of the 97 (41%) in the colporrhaphy group and 14 of 105 (13%) in the mesh group ($P < .0001$). The number needed to treat was thus 4. The proportion of symptomatic patients, including those with dyspareunia, did not differ between the groups. The mesh erosion rate was 19%.

CONCLUSION: At 3 year follow-up, anterior colporrhaphy with mesh reinforcement significantly reduced anatomic recurrences of anterior vaginal prolapse, but no difference in symptomatic recurrence were noted and the mesh erosion rate was high. The use of mesh was not associated with an increase in dyspareunia.

Key words: cystocele, pelvic organ prolapse, polypropylene mesh, sexual function, vaginal surgery

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Almost 10% of women need surgery for pelvic organ prolapse, urinary incontinence, or both during their lifetime, and 30% of them will undergo 2 or more surgical procedures.[1] Prolapse of the anterior vaginal wall (cystocele) is the most common and typical segment requiring surgical repair. It has traditionally been treated with anterior colporrhaphy, which entails central plication of the fibromuscular layer of the anterior vaginal wall.[2] Recurrent anterior vaginal wall prolapse after conventional repair has occurred in more than 30% of the cases.[3]

In an effort to improve outcomes in transvaginal prolapse repair, a number of biologic and synthetic graft materials have been introduced to complement, reinforce, or replace native tissue in reconstructive surgical procedures. The use of synthetic graft material for repair of the anterior vaginal wall prolapse has been limited by possible adverse events related to the mesh (ie, graft erosion, dyspareunia, pelvic pain, and urinary incontinence). The literature on graft use is increasing, but there are few randomized controlled trials comparing the efficacy of transvaginal prolapse repair with or without graft material.[4-7]

We here conducted a prospective randomized study with a 3 year follow-up to determine whether reinforcement of traditional anterior colporrhaphy with a synthetic polypropylene mesh would reduce the frequency of recurrences in women with anterior vaginal wall prolapse and to explore whether synthetic mesh is associated with any adverse effects. The outcomes of 12 and 24 month follow-up have been reported previously.[8,9]

Materials and Methods

Participants were recruited from the Departments of Obstetrics and Gynecology at 4 central hospitals and 1 university hospital in Finland between April 2003 and May 2005. The institutional review board approved the study protocol in each hospital.

Women with symptomatic anterior vaginal wall prolapse to the hymen or beyond and referred for reconstructive pelvic surgery were eligible for inclusion. Patients requiring concomitant vaginal vault suspension such as sacrospinous ligament fixation or sacrocolpopexy for vaginal prolapse or uterine procidentia or surgery for stress urinary incontinence or laparotomy or laparoscopy for any reason were excluded. Undergoing other prolapse repairs did not preclude study participation and did not affect group assignment.

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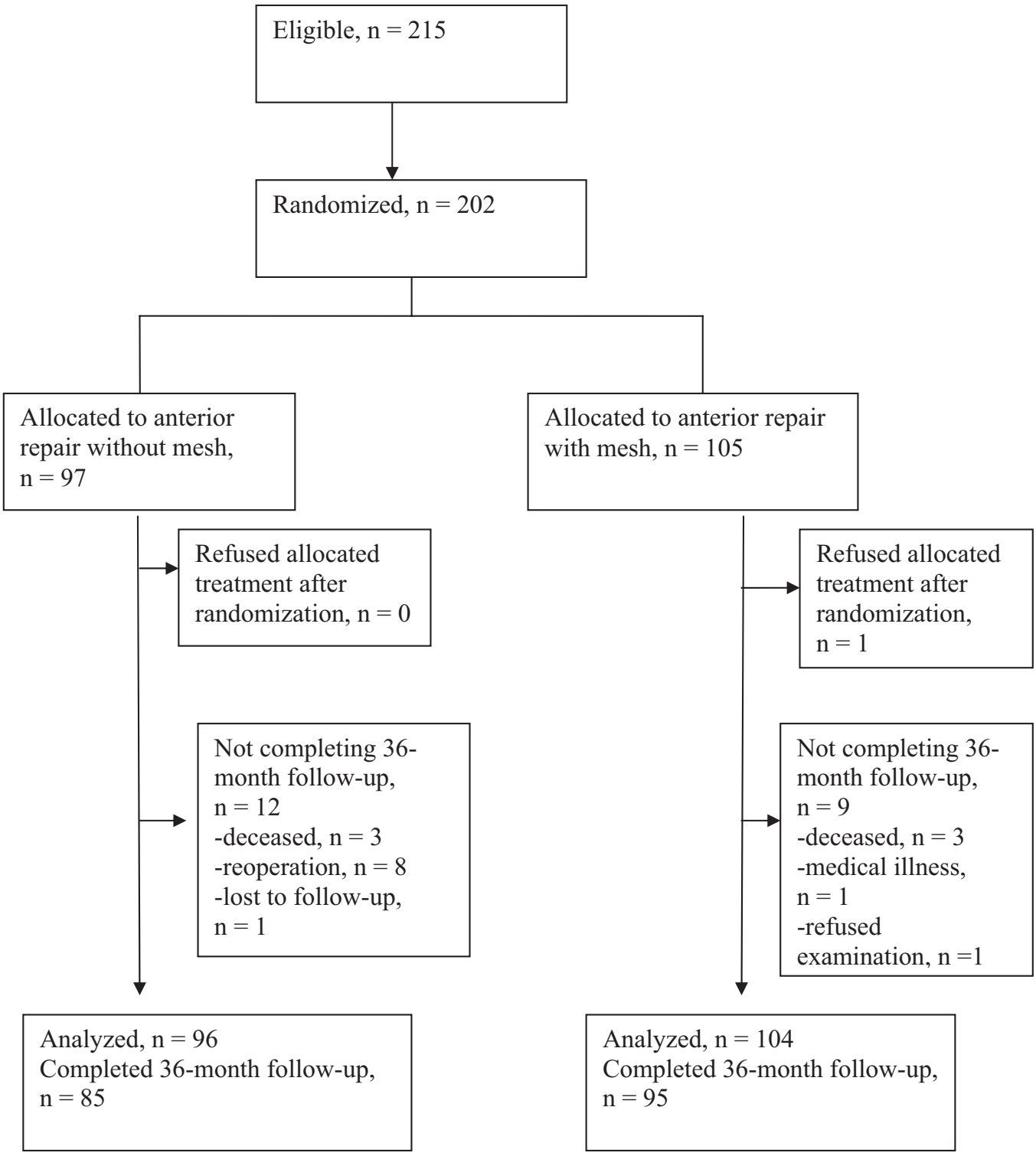
FIGURE 1
Trial flow diagram, including total sample size, enrollment, randomization, follow-up, and analysis



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