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MULTICENTER PROSPECTIVE TRIAL OF COLPEXIN® SPHERES IN WOMEN WITH ADVANCED GENITAL PROLAPSE

Hypothesis / aims of study
To determine the safety and effectiveness of the Colpexin® Sphere, an intra-vaginal device for women with advanced genital prolapse.

Study design, materials and methods
Women with ≥ stage 3 vaginal prolapse enrolled in a 16-week clinical trial and used a sphere continuously while performing Kegel exercises. As pelvic floor tone increased, smaller devices were used. Primary outcome measures included ease of insertion and removal, ease of achieving comfort, maintenance of sphere position during daily activities, change in pelvic floor tone and contractility, improvement in quality of life and satisfaction questionnaires, and safety. Secondary outcome measures were change in urinary incontinence (if pre-existing) and voiding function.

Results
Thirty-nine subjects with mean age 59.21 ± 12.88 years (range 30-79) enrolled at three test sites. Twenty (51.2%) had SUI at study entry. Twenty-seven (69.2%) completed the 16-week study, with 15 (55.6%) continuing long-term. Patient questionnaires reported satisfactory ease of insertion (96.3%) and removal (100%), ease of achieving comfort (89%), and maintenance of sphere position during daily activities (70.4%). Displacement of the device with defecation was reported in 72.0%, but remedied by supporting the device during, or removal prior to defecation. Pelvic floor assessment and Colpexin® pull test* (at 16 weeks) showed enhanced pelvic floor muscle strength. Seventeen subjects (63.0%) showed increased muscle function during digital exam in the parameters of pressure, duration, and/or displacement. Pull test values demonstrated a significant improvement in pelvic floor muscle contractility compared to baseline. Voiding function was unaffected. Maximum flow rate, flow time and PVR values at baseline were statistically similar to 16 week values. Incontinence Impact Questionnaire scores showed no significant difference from baseline to 16 weeks. Urogenital Distress Inventory ratings of irritative and stress symptoms showed statistically significant improvements from baseline to 16 weeks (P=0.0002). Of the twenty subjects with pre-existing urinary incontinence, 75% were dry or improved at 16 weeks and 25% experienced no change. Sixty-two percent of subjects said they would wear the Colpexin® Sphere to treat urine loss alone. Ninety-three percent of subjects would recommend the Colpexin® Sphere to treat POP.

Interpretation of results
Advanced genital prolapse is considered a contraindication to physiotherapy for pelvic floor dysfunction. Using an intravaginal Colpexin sphere to support the existent prolapse above the levator musculature allowed for physiotherapy to benefit patients with exteriorized prolapse, and improve their voiding function. Motivated patients found this treatment option very attractive.

Concluding message
The Colpexin® Sphere represents an innovative way to manage POP and concomitant bladder dysfunction. The ideal candidate has the desire and ability to achieve pelvic floor muscle recovery with treatment of coexisting SUI through pelvic floor muscle rehabilitation.

* Initial experience with a new method for the dynamic assessment of pelvic floor function in women: the Kolpexin Pull Test. Int Urogyn J 2004;15:39-43