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EFFECT OF COLPEXIN SPHERE ON PELVIC FLOOR MUSCLE STRENGTH IN WOMEN WITH PELVIC ORGAN PROLAPSE: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

Pelvic organ prolapse (POP) is a major problem and common condition, with variation of prevalence rate from 41% to 51% of women over the age of 40 years. Physical and interventions are often used in cases of mild to moderate prolapse. Colpexin™ Sphere (ADAMED Ltd., Warsaw, Poland) is a removable intravaginal device designed to reduce POP while positioned above the levator ani and to facilitate concomitant pelvic floor muscle strengthening through pelvic floor exercises (1). The device was developed in Europe, where extensive clinical experience has been achieved during the last 10 years. Since there are no studies comparing Colpexin™ Sphere with conventional treatment, our objective was to assess the effect of Colpexin™ Sphere in women with pelvic organ prolapse stage I & II on improving pelvic floor muscle strength compared with the pelvic floor exercise only by using digital test and Colpexin pull test.

Study design, materials and methods

It was a single blind, randomized controlled trial. We aimed to recruit 90 women with pelvic organ prolapse stage I & II, giving 90% power (α = 5%) to detect the difference in Colpexin™ pull test and digital test of pelvic floor muscle strength between the two groups. The sample size calculation is based on previous research carried out by Lukban JC, et al (2). Participants were women with pelvic organ prolapse stage I & II according to the pelvic organ prolapse quantitation system (POP-Q) with the age or 20 or over. They were randomly divided into 2 groups, one group used Colpexin™ Sphere with pelvic floor muscle exercise and the other group did pelvic floor exercise only for a 16-week period. All participants were taught about home based practice with booklet of pelvic floor exercise. They were asked to tighten the pelvic floor muscles and hold for 10 seconds, then relax 10 seconds and do 10 repetitions of this exercise three times a day at home. The study group was given Colpexin Sphere and instructed on device insertion and removal with practicing pelvic floor exercise, and the control group practicing pelvic floor exercise alone. The efficacy were evaluated as a baseline, 4, 8, 12 and 16-week after treatment for comparison of pelvic floor muscle strength assessment. The first main outcome measure was the Colpexin™ pull test (3). The second main outcome measure was the digital test assessed with Brink scale. The participants were examined by the same investigators who were not aware of the participants' group. For all the comparisons made in this study, $P < 0.05$ was the value regarded as statistically significant.

Results

A total of 91 participants were randomized and 85 participants completed the study with the compliances above 80%. At baseline, there were no significant differences between the groups in any of background characteristics such as age, body mass index, parity and menopausal status. More than half of women experienced vaginal discomfort or being aware of a lump coming down in her vagina or feeling that her vagina was too loose.

The Colpexin™ pull test showed no statistically significant difference in both groups, but at the end of the study, the muscle strength were significantly increased in both groups (Table 1) with mean baseline Colpexin™ pull test contraction value of 15.38 ± 4.94 N, which increased to a mean of 19.15 ± 7.11 N in women wearing Colpexin™ Sphere with pelvic floor exercise, and mean baseline value of 15.05 ± 6.78 N increased to a mean of 18.37 ± 8.91 N in women who did pelvic floor exercise only. The Colpexin™ Pull test value significantly increased after the first 4 weeks of treatment in the study group.

Regarding the digital test, it showed statistically significant increases in both groups after treatment, the difference between the 2 groups was not demonstrated. The median Brink scale increased from 8 to 10 and from 7 to 9 in the study group and the control group, respectively.

Most of the women, who had been wearing Colpexin™ Sphere, reported high satisfaction of using this device with her pelvic floor exercise and would recommend the device to others for assisting pelvic floor exercise practice. Some women experienced displacement of the device with defecation.

Table 1 Colpexin Pull Test Values

Duration of treatment	Study Group (N=42)	Control Group (N=43)
At baseline	15.38 ± 4.94	15.05 ± 6.78
4 weeks	16.69 ± 5.51*	15.57 ± 6.95
8 weeks	18.31 ± 6.14*	16.30 ± 7.72*
12 weeks	18.61 ± 6.63*	17.64 ± 8.01*
16 weeks	19.15 ± 7.11*	18.37 ± 8.91*

No significant difference between two groups
*There was statistically significant difference compared to baseline.

Interpretation of results

This is the first study about the effect of the Colpexin™ Sphere on improving pelvic floor muscle strength in women with early stage pelvic organ prolapse compared to the pelvic floor exercise only. The results obtained in this study demonstrated that pelvic floor exercises associated with or without Colpexin™ Sphere are effective in overall pelvic floor muscle contraction strength which was documented on digital test and Colpexin™ pull test data. The pelvic floor muscle strength in women using Colpexin™ sphere increased significantly as early as 4 weeks after treatment. It may be explained by a mechanism of Colpexin™ sphere device that requires the women to actively perform pelvic floor contractions to keep it in place. If a woman cannot perform pelvic floor contractions correctly the device will not remain in place and may be easily expelled.

Concluding message

In conclusion, even though Colpexin^{TM} Sphere plus pelvic floor exercise improved pelvic floor muscle strength assessed with Colpexin pull test and digital test in women with stage I and II pelvic organ prolapse, the improvement was not statistically different from exercise alone over a 16-week period. However, Colpexin^{TM} sphere may aid women to improve the strength of pelvic floor muscle as early as 4 weeks after treatment.

References

1. Adamkiewicz MM, Adamkiewicz MF, Jozwik M, Jozwik M. Combined treatment of pelvic floor exercises and new intravaginal device for genital prolapse. Int Urogynecol J 2001; 12(Suppl 3):48.
2. Lukban JC, Aguirre OA, Davila GW, Sand PK. Safety and effectiveness of Colpexin Sphere in the treatment of pelvic organ prolapse. Int Urogynecol J 2006; 17:449-454.
3. Guerette N, Neimark M, Kopka SL, Jones JE, Davila GW Initial experience with a new method for the dynamic assessment of pelvic floor function in women; the Kolpexin Pull Test. Int Urogynecol J 2004; 15:39-43.

Specify source of funding or grant	**Faculty of Mediicine, Ramathibodi Hospital, Mahidol University**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects of Faculty of Medicine, Ramathibodi Hospital, Mahidol University**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**