Randomized Comparison of Vaginal and Suprapubic Surgical Methods in the Treatment of Urinary Stress Incontinence in Iran

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Citation

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Abstract

Objective: Comparison of vaginal (Kelly operation) versus suprapubic (Raz operation) in the surgical treatment of urinary stress incontinence.

Material and Methods: In a randomized clinical trial, 36 women suffering from urinary stress incontinence with confirmed bladder neck hypermobility by Q tip test were included in the study after getting their written consent. Patients were randomly divided into two groups of vaginal and supra pubic (18 cases in each group). Postoperative follow up of recurrence and continuation of treatment response was done for 21 months.

Results: Six recurrence cases were observed in suprapubic group and 11 in vaginal group. Mean continuation of treatment response was 17.4 and 11.6 months in supra pubic and vaginal groups. Probability of continuation of treatment response up to 21 months after surgery was 23% in supra pubic and 29% in vaginal groups. Continuation of treatment response between groups was not significant (long-rank test).

Conclusion: Continuation of treatment response up to 21 months was low and was not significantly different in both supra pubic and vaginal groups.

INTRODUCTION

Stress incontinence is due to anatomic hypermobility (leading to defect in urethral closure in stress) as weak interval factors.[1]Anatomic incontinence is the most common type of stress incontinence and treatable by surgery. Success rate of anterior culporaphy in the treatment of stress incontinence is low and supra pubic procedure like Raz and Burch operations usually show better results.[1] Primary response rate in needle suspension is 70-90% significantly and 5 year success is 50% or less. [2] Suture material is important in this kind of operation and absorbable materials increase the probability of recurrence. [1]

In a retrospective study on 206 women with urinary stress in continence, treated by Raz operation, 90% of them revealed successful results in a 15 months follow up [3]. Continuation of treatment response following Raz operation is reported to be 65-95% in the other studies. [3] Long term success rate of anterior culporaphy methods in the treatment of urinary stress incontinence is 35-65% ([2], [4], [5]).

The present study is to compare supra pubic (RAZ) versus vaginal Kelly suture with regards to the continuation of treatment response in patients suffering from urinary stress incontinence in Fatemieh Hospital of Hamadan.

MATERIAL AND METHODS

A randomized clinical trial done was conducted on women suffering from urinary stress incontinence in Fatemieh Hospital of Hamadan. Inclusion criteria were confirmed bladder neck hypermobility by Q tip test, lack of history of previous surgery for treatment of urinary stress incontinence, negative urine culture, and being in the age of reproduction (up to 44 and non-menopausal).

In the case of urinary tract infection, reevaluation was done after antibiotic therapy and the final decision was made. Patients with systemic disease such as diabetes, chronic pulmonary disease, and neuro-degenerative disease were

excluded from the study.

Thirty six appropriate for study patients were included in the study in two randomized arms of treatment after getting their written consents (approved by university ethical committee). In the vaginal group (n = 18), anterior culporaphy including two bites of Kelly suture using Vicryl No. 0 suture material was done. In the suprapubic group (n = 18), Raz operation using two loops of suspension using Nylon No. 1 was done.

The sample size was calculated to be able to show a difference of 20% in continuation of treatment response between two groups with a power of 90% and with = 0.05. The patients were followed up for 2 years with 3-month interval. The followups were focused on recurrence and continuation of treatment response. In the case with other urinary symptoms, urinalysis, urine culture, and treatment of urinary tract infection were done and finally clinical decision of recurrence or continuation of treatment response was made. If necessary, active follow up by telephone or address was done. If the patients complained of urinary stress incontinence in the follow-ups, recurrence would be diagnosed.

The probability of continuation of treatment response in the follow up was calculated by life table analysis and comparison of probability treatment response was tested in the two groups by log-rank test at the level of = 0.05.

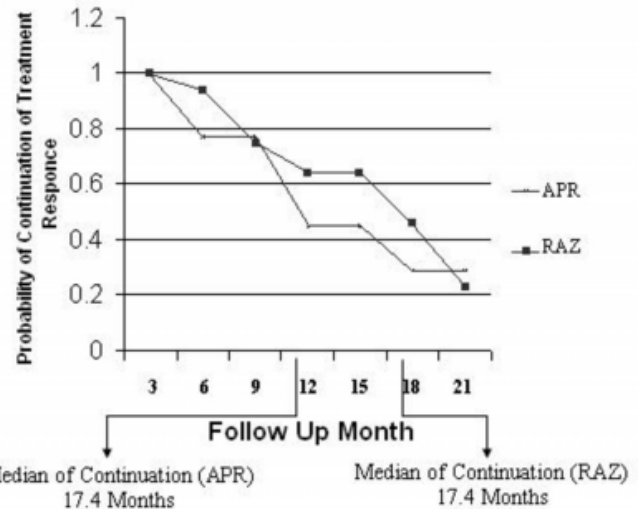
RESULTS

The two groups were similar regarding age and parity. The present study revealed 17 recurrence cases of which 6 were in the supra pubic group and 11 in the vaginal group. Median of follow up period in suprapubic group was 9 months and in vaginal group was 12 months with a range of 6-12 months. All the patients were followed up for at least 6 months. Median of continuation of treatment response was 17.4 months in the suprapubic group and 11.6 in the vaginal group.

Probability of continuation of treatment response up to sixth month was 94% in the supra pubic group and 77% in the vaginal group. The probability up to the 12th month were 64% and 45% and up to 21st month were 23% and 29%. (Figure 1). Comparison of treatment response in two groups did not reveal any significant difference.

Figure 1

Figure 1: comparison between the probability of continuation of treatment response in two surgical methods



DISCUSSION

The patients in the two groups suffered from urinary stress incontinence due to bladder neck hypermobility, confirmed by Q tip test. All of them were in reproductive age. Median continuation of treatment response seemed higher in the supra pubic group (17.4 months versus 11.6 months). Probably of continuation of treatment response up to one year in the suprapubic group was higher in comparison to the vaginal group. However, the probabilities of treatment response up to 21st month were close to each other. The recurrence in the supra pubic group was later than it was in the vaginal group. Finally the two groups did not show any significant difference regarding probability of continuation treatment response.

Continuation of treatment response of both groups in the present study was lower than the other studies. In a retrospective study on 206 cases, response rate of supra pubic surgery up to 15th moth was 90% [3] while in our study it was 64%. In addition Bergman and colleagues showed probability of continuation of treatment response of 72% in the supra pubic and 65% in the vaginal group up to 12 months[1] while in our study these numbers were 64% and 45%, respectively. Some part of this difference may be due to study design because in the present study, if the patient revealed stress incontinence in lesser degree in comparison to her stress incontinence before the operation, the difference would be ignored and she would be considered a case of recurrence and discontinuation of treatment response. In other words we did not grade urinary stress in continence

based on its severity. In some other studies grading of mild, moderate and severe incontinence are observed. So, treatment response is evaluated according to the above-mentioned grading. On the other hand, urodynamic study was not done on our patients.

In conclusion, the present study indicates that Raz(suprapubic) and Kelly(vaginal) repair operations in the treatment of urinary stress incontinence are not different with each other up to the 21st month and the probability of continuation of treatment response until the 21st month is low and similar to each other in both groups.

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