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## Longitudinal trends with Improvement in Quality of Life after TVT, TVT O and Burch Colposuspension Procedures

### Authors' Contribution:

- A** Study Design
- B** Data Collection
- C** Statistical Analysis
- D** Data Interpretation
- E** Manuscript Preparation
- F** Literature Search
- G** Funds Collection

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### Background:

### Summary

Comparison of the quality of life (QoL) trends after TVT, TVT O and Burch colposuspension (BCS) procedures and comparison of long-term subjective and objective outcomes.

### Material/Methods:

The study included 215 women who underwent a TVT, TVT O or BCS procedure. We monitored QoL after each procedure and the effect of complications on the QoL as assessed by the IQOL questionnaire over a 3-year period.

### Results:

The study was completed by 74.5% of women after TVT, 74.5% after TVT O, and 65.2% after BCS procedure.

In the long-term, the QoL improved from 46.9 to 88.7 and remained stable after BCS; after TVT and TVT O, it declined, but only after TVT O was the decline statistically significant compared to BCS.

The IQOL for women with post-operative complications has a clear descending tendency. The effect of the complications is highly significant ( $p < 0.001$ ). Only the OAB complication had a statistically significant effect on QoL  $p < 0.001$ . Preexistent OAB does not negatively affect postoperative results of anti-incontinence surgery.

### Conclusions:

There was a statistically significant decline with the longitudinal values of IQOL with TVT O, but not with TVT or BCS. Anti-incontinence operations significantly improve quality of life for women with MI, but compared to the SI group, the quality of life is worse when measured at a longer time interval after the operation. Anti-incontinence operations significantly improve quality of life, and the difference in preoperative status in the long-term follow-up is demonstrable.

### key words:

**anti-incontinence surgery • Burch colposuspension • Incontinence Quality of Life • long-term results • Mixed Incontinence • Stress Urinary Incontinence • TVT • TVT O**

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## BACKGROUND

Stress urinary incontinence [1,2] is a common problem which affects a high percentage of women [3]. In addition to pelvic floor muscles exercise, surgery has played an important role in the treatment of stress urinary incontinence (SUI). It should be possible to offer a surgical procedure which is highly effective, safe and has good long-term outcome.

Burch colposuspension (BCS) was considered a gold standard in anti-incontinence surgery, with good long-term results [4]. Many studies have confirmed its cure rate at 69–88% [3–5]. However, over the past decade this procedure has been largely replaced by the application of various types of TVTs (tension-free vaginal tapes) [6–11]. TVT and colposuspension achieve similar success rates in treating stress incontinence [12,13]. There have not been many long-term studies dealing with the occurrence of complications and quality of life after anti-incontinence operations. The majority of studies assess the final condition of the patients, while the comparison of objective and subjective information is always an issue. Our study focused on comparing developments in the quality of life and the occurrence of complications in a long-term follow-up after TVT, TVT O and BCS. For subjective assessment of urinary incontinence, we have chosen a validated specialized Incontinence Quality of Life questionnaire (IQOL) [14], which is brief and comprehensive, for diagnosing urinary incontinence and OAB in women.

The aim of our study was to monitor the trends in quality of life after TVT, TVT O and BCS procedures, and to establish whether the occurrence of complications affects the quality of life (QoL).

## MATERIAL AND METHODS

This prospective observational study included 215 women who underwent surgical treatment for stress urinary incontinence between January 2002 and December 2005. The study was approved by the local ethics committee. Before enrollment, all subjects gave written consent to their inclusion in the study. Final data have been processed for 154 (71.6%) women who underwent all controls according to the prepared protocol. Before surgery, the women filled in the IQOL questionnaire, their case history was taken, and they underwent a complete urogynecological examination: clinical examination, transperineal ultrasound (using an Acuson 128 XP10, Voluson 730 Expert, GE HealthCare, convex probe 3.5/5MHz), complete urodynamic examination (filling cystometry, profilometry, uroflowmetry – using Dantec duet Meditronics and later Uromics 7 B-K Medical A/S equipment) and 3-day voiding diary [2,15]. All women who underwent the operation had urodynamic stress urinary incontinence. Mixed type of incontinence with predominant stress type was not an exclusion criterion from the study. Exclusion criteria were pelvic organ prolapse >1<sup>st</sup> stadium using pelvic organ prolapse quantification system POP-Q [16], predominant urgency incontinence, and post-void residual volume (PVR) greater than 100 mL. Surgery was only offered if conservative therapy was unsuccessful. Women with concomitant operations were also excluded from the study.

TVT procedure (Gynecare TVT, Ethicon, Inc. Piscataway, NJ, USA) was carried out as recommended by Ulmsten [7]. TVT O (Gynecare, TVT Obturator System Ethicon, Inc. Sommerville, NJ, USA) was applied as per de Leval, inside-out approach [17]. For colposuspension, the cavum Retzii was entered by means of a Pfannenstiel incision, and 2 non-absorbable stitches were applied through the pubocervical fascia and vagina paraurethraly, at the point of urethro-vaginal junction (Gynecare, Nurolon Ethicon Inc. Sommerville, NJ, USA) approximately 2 cm from the middle line. Surgical procedures were indicated consecutively.

Post-operative follow-up was carried out 3 months, 1 year and 3 years after surgery. Apart from the urodynamic examination, the procedure was the same as before surgery. Objective cure rate was determined based on a negative stress test performed in supine and in standing positions during the gynecologic examination.

The women were divided into groups by the type of surgical procedure. Patients were not randomized, and surgical procedure was mainly based on surgeon decision and in some cases on patient preference.

Occurrence of different complications and their effects on QoL was monitored. For statistical processing, the symptoms monitored were divided into 4 groups as follows: 1) the first group was the OAB group; the second group included patients with recurrent stress incontinence; 2) the pain group included patients complaining of pain and dyspareunia; 3) the descent group included cystocele, rectocele; 4) the other symptoms group included leakage at sexual intercourse, protrusion, voiding difficulty or urinary tract infections. Re-operations due to failed primary operation or serious complications, or other re-operations as a result of descent, have been recorded.

## Statistical analysis

Data were analyzed and processed using R freeware [18]; tests were carried out either non-parametrically (where a single period was monitored), or using mixed linear models (the effect of the factor being monitored on IQOL), at a 5% significance level. 95% confidence intervals were based on Wald's test. Other processes used included Pearson's chi-square test, Kruskal-Wallis chi-square test, regression curve, Bonferroni method to ascertain the effect of complications on IQOL, Wilcoxon test and Fisher's exact test.

The major methodological limitation of the study is non-randomization of the surgical procedures.

## RESULTS

Complete data were obtained for 154 women (71.6% of the original group); 74.5% of women after TVT, 74.5% after TVT O procedure and 65.2% after BCS completed the study; 47 women were excluded from the study due to incomplete data, 12 women refused further cooperation, 1 woman died and 1 woman experienced recurrence of cervical cancer. Median follow-up was 3.1 years, SD  $\pm 0.56$  years. The mean age of the group monitored was 54.7, SD  $\pm 9.9$  years (range from 32 to 81) (Table 1). The women who underwent BCS were significantly younger than the women who underwent other procedures ( $p < 0.001$ ). No difference between individual

**Table 1.** Basic characteristics of the study group.

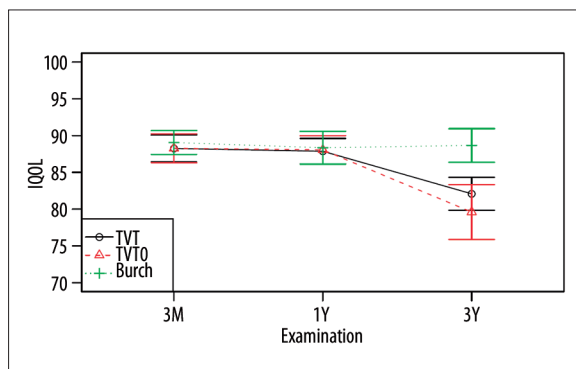
	N (%)*	Mean age (SD)	Mean BMI (SD)	MUI Patient N(%)
TVT	76 (74.5%)	57.2 (10.8)	26.9 (4.7)	20 (26.3%)
TVT O	35 (74.5%)	56.2 (9.3)	28.3 (4.4)	11 (31.4%)
BU	43 (65.2%)	49.1 (6.0)**	26.7 (4.2)	15 (34.9%)
Total	154/215 (71.6%)	54.7 (9.9)	27.2 (4.5)	46 (29.9%)

\* Number of women who completed the study; \*\*  $p < 0.005$  women from BU group are significantly younger. TVT, TVT O – tension free vaginal tape, TVT obturator; BU – Burch colposuspension; BMI – body mass index; MUI – mixed urinary incontinence.

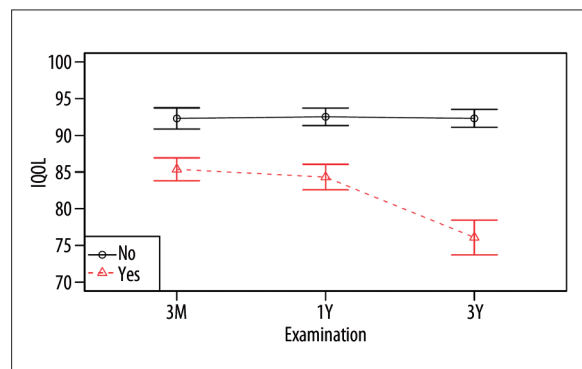
**Table 2.** Mean values of IQOL questionnaire during the study period.

	Before	3M	1Y	3Y
	IQOL (SD)	IQOL (SD)	IQOL (SD)	IQOL (SD)
TVT (76)	45.2 (19.2)	88.2 (16.1)	87.9 (15.1)	82.1 (19.5)**
TVT O (35)	47.0 (16.8)	88.3 (11.6)	88.1 (11.5)	79.6 (22.1)*,**
BU (43)	46.9 (20.8)	89.1 (10.6)	88.3 (14.6)	88.7 (14.9)*,**
SUI (108)	46.9 (19.1)	89.0 (13.5)	89.4 (13.2)#	85.5 (17.9)#
MUI (46)	44.1 (18.9)	87.4 (14.3)	84.8 (15.8)#	78.4 (21.4)#

Before – before surgery; 3M – three months after surgery; 1Y – one year after surgery; 3Y –three years after surgery.  $p < 0.001$  the impact of anti-incontinent surgery is statistically significant in every examination after surgery during whole monitored period. TVT, TVT O – tension free vaginal tapes; BU – Burch colposuspension; SUI – stress urinary incontinence; MUI – mixed urinary incontinence. \*  $p = 0.006$  effect of TVT O and BU on IQOL; \*\* Kruskal Wallis  $p = 0.051$  the difference only just fails to be statistically significant; # Wilcoxon test  $p = 0.03$  the difference of IQOL between MUI and SUI is significant; ## Wilcoxon test  $p = 0.032$  the difference of IQOL between MUI and SUI is significant. # and ## the difference between controls is demonstrable.



**Figure 1.** Post- operative trend of QoL after TVT, TVT O and Burch colposuspension. Error bars of IQOL in monitored period (average values and standard errors).



**Figure 2.** Comparison of QoL trend after surgery in women with or without any complications. Error bars of IQOL in monitored period (average values and standard errors).

operation groups as regards BMI and parity could be proven at a 5% significance level. The preoperative IQOL questionnaire did not differ for individual surgical procedures.

Objective cure rate (negative stress test) at the end of the follow-up period for the TVT group was 89.5%, 85.7% for TVT O, and 90.7% for BCS: differences were not statistically significant. The quality of life improved with surgery (46.9 to 89.1 with BCS, 45.2 to 88.2 with TVT and 47.0 to 88.3 with TVT O) and then remained statistically significantly improved against the pre-operative condition for the whole monitored

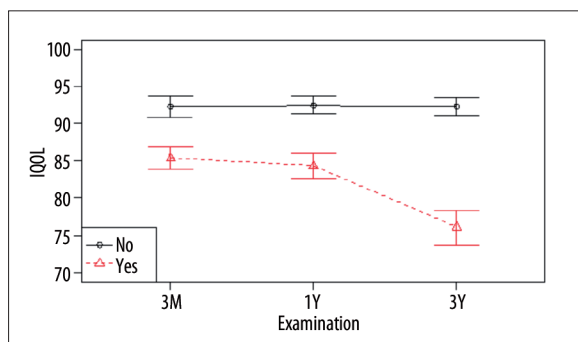
period for all 3 procedures:  $p < 0.001$  (Table 2). Three years after surgery, differences between the procedures for IQOL were not statistically significant ( $p = 0.051$ ). Subjective satisfaction as per the total value ascertained in the IQOL questionnaire was 82.1 for TVT, 79.6 for TVT O and 88.7 for BCS.

In the long-term, the QoL remain stable after BCS procedure, but after TVT and TVT O it declined (Figure 1). Only after TVT O was the decline statistically significant compared to BCS ( $p = 0.006$ ). The initial difference grew by 3.4 points each year after the operation (95% confidence interval is 1.0 to 5.9).

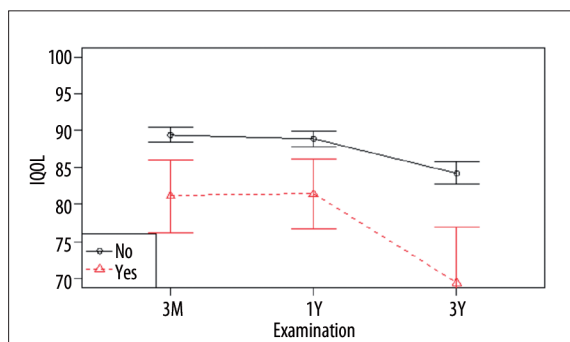
**Table 3.** Average values of IQOL questionnaire after surgery in patient with complications.

Complications	3M		1Y		3Y	
	N (%)	IQOL (SD)	N (%)	IQOL (SD)	N (%)	IQOL (SD)
Without any complication	69 (44.8%)	92.3 (12.0)	70 (45.5%)	92.5 (10.0)	69 (44.8%)	92.3 (10.1)
With any complication	85 (55.2%)	85.4 (14.3)	84 (54.5%)	84.3 (16.0)	85 (55.2%)	76.1 (21.7)
OAB*	55 (35.7%)	83.4 (14.6)	50 (32.5%)	81.6 (18.2)	65 (42.2%)	73.2 (22.2)
Recurrence of SUI	15 (9.7%)	86.7 (14.4)	16 (10.4%)	83.6 (14.7)	17 (11.0%)	75.5 (18.1)
Pain	8 (5.2%)	87.8 (8.3)	8 (5.2%)	91.1 (8.9)	6 (3.9%)	91.3 (9.7)
Prolapse	21 (13.6%)	83.2 (12.7)	24 (15.6%)	86.6 (10.9)	14 (9.1%)	83.6 (19.4)
Other complications	18 (11.7%)	81.1 (20.8)	17 (11.0%)	81.4 (19.3)	9 (5.8%)	69.3 (23.7)

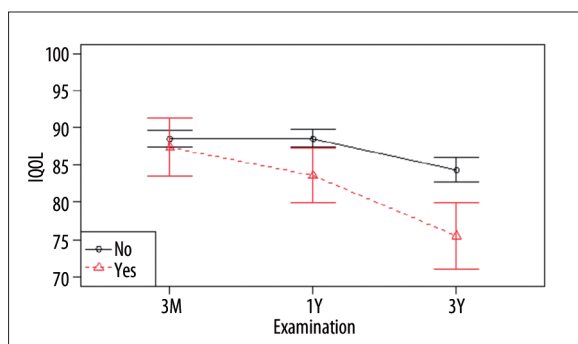
SUI – stress urinary incontinence; 3M – three months after surgery; 1Y – one year after surgery; 3Y –three years after surgery. Other complication: leakage at sexual intercourse, protrusion, voiding difficulty or urinary tract infections. \* Including of symptoms urgency, urgency *de novo*, frequency, nocturia, and UUI.



**Figure 3.** Comparison of QoL trend after surgery in women with or without complication OAB. Error bars of IQOL in monitored period (average values and standard errors).



**Figure 5.** Comparison of QoL trend after surgery in women with or without complications in group others symptoms included leakage at sexual intercourse, protrusion, voiding difficulty or urinary tract infections. Error bars of IQOL in monitored period (average values and standard errors).



**Figure 4.** Comparison of QoL trend after surgery in women with or without complication recurrent SUI. Error bars of IQOL in monitored period (average values and standard errors).

The IQOL for women with post-operative complications has a clear descending tendency (Figure 2). This interaction is proved by the test in the mixed effects model ( $p=0.013$ ). The effect of the complications is highly significant ( $p<0.001$ ). The complications do not occur equally over the monitored period (Table 3). If we monitor individual complications and

IQOL, the graph analysis displayed in Figures 3–5 indicates a significant effect for OAB, recurring stress incontinence and other complications. However, OAB is the only complication with statistical significance ( $p<0.001$ ). Occurrence of complications does not depend on the type of operation (chi square 2.04,  $p=0.36$ ). All symptoms and complications that were monitored are depicted in Table 4.

Preoperatively, 29.9% of women suffered from mixed incontinence. OAB symptoms for these patients dropped to 56.5%, 45.7% and 56.5% at 3 months, 1 year and 3 years, respectively, after the procedure. Overall prevalence of OAB symptoms after procedure at 3 months was 35.7%, at 1 year 32.5%, and at the end of the survey 42.2% (Table 4). *De novo* anticholinergic use was postoperatively noted in 5 patients (4.6%) 3 months after surgery, 10 patients 1 year afterwards (9.3%), and 16 patients (14.8%) at the end of survey. The relatively high prevalence of OAB, which is uncommon, is due to registration of every complaint of OAB in the urinary diary. Most of these OAB did not influence the QoL and were not obligatory. The low rate of pharmacological

**Table 4.** Summary of late postoperative complications after TVT, TVT O and Burch colposuspension in the study period.

	3M				1Y				3Y			
	AII N (%)	TVT N (%)	TVT O N (%)	BUN (%)	AII N (%)	TVT N (%)	TVT O N (%)	BUN (%)	AII N (%)	TVT N (%)	TVT O (%)	BUN (%)
OAB	55 (35.7%)	18 (23.7%)	19 (54.3%)	18 (41.9%)	50 (32.5%)	23 (30.3%)	13 (37.1%)	14 (32.6%)	65 (42.2%)	31 (40.8%)	16 (45.7%)	18 (41.9%)
Recurrent SUI	15 (9.7%)	8 (10.5%)	5 (14.3%)	2 (4.7%)	16 (10.4%)	9 (11.8%)	4 (11.4%)	3 (7.0%)	17 (11%)	8 (10.5%)	5 (14.3%)	4 (9.3%)
Tape protrusion	5 (3.2%)	4 (5.3%)	1 (2.9%)	0	6 (3.9%)	5 (6.6%)	0	1 (2.3%)	5 (3.2%)	2 (2.6%)	3 (8.6%)	0
Dyspareunia	7 (4.5%)	4 (5.3%)	1 (2.9%)	2 (4.7%)	5 (3.2%)	4 (5.3%)	0	1 (2.3%)	5 (3.2%)	4 (5.3%)	1 (2.9%)	0
Rectocele	14 (9.1%)	4 (5.3%)	3 (8.6%)	7 (16.3%)	17 (11%)	9 (11.8%)	2 (5.7%)	6 (14.0%)	12 (7.8%)	5 (6.6%)	3 (8.6%)	4 (9.3%)
Cystocele	11 (7.1%)	1 (1.3%)	1 (2.9%)	9 (20.9%)	12 (7.8%)	5 (6.6%)	0	7 (16.3%)	9 (5.8%)	3 (3.9%)	1 (2.9%)	5 (11.6%)
UUI	3 (1.9%)	1 (1.3%)	1 (2.9%)	1 (2.3%)	9 (5.8%)	5 (6.6%)	0	4 (9.3%)	11 (7.1%)	5 (6.6%)	5 (14.3%)	1 (2.3%)
Urinary tract infection	8 (5.2%)	4 (5.3%)	3 (8.6%)	1 (2.3%)	9 (5.8%)	5 (6.6%)	1 (2.9%)	3 (7.0%)	4 (2.6%)	2 (2.6%)	1 (2.9%)	1 (2.3%)

therapy suggests an underestimation of OAB symptoms after surgery. Most OAB, such as post-operative inflammation of the urinary bladder, are solved by the physicians.

## DISCUSSION

Anti-incontinence operations significantly improve quality of life. The quality of life remained significantly improved against the pre-operative condition for the whole monitored period for all 3 procedures. Objective cure rate and subjective satisfaction are comparable with other published studies [13,19–24]. In the long-term after the operation, colposuspension was rated best, both subjectively and objectively. The IQOL deterioration in the TVT O group was more demonstrable than in the BCS group. If we had used a more simplified evaluation, with terms such as “cured”, “improvement” and “failure”, it would have been impossible to find any differences between the procedures. However, while the values of IQOL among groups TVT, TVT O and BCS were not statistically significant at the end of the survey, there were differences in deterioration development trends of QoL.

Some of the women who underwent Burch colposuspension also had concomitant surgery for abdominal hysterectomy, which may explain the difference in age compared to women after the TVT procedure. This fact alone, however, cannot explain the differences in the QoL after surgery. The monitoring of QoL after surgery in the long-term is important because *de novo* symptoms and complications vary over time.

We noted the effect of complications on the quality of life in our study. However, OAB is the only complication that statistically significantly influences the QoL. Occurrence of other complications is too low to obtain statistically significant differences. Compared to previously published studies, the prevalence of OAB was similar [20–24].

We agree that preexistent OAB does not negatively affect postoperative results of anti-incontinence operations [24,25]. Unlike other studies [26–28], before surgery we did not

confirm statistically significantly worse quality of life for women with mixed incontinence compared to those with stress urinary incontinence. This may be due to the fact then we indicated women for the operation with predominant stress urinary incontinence; patients with predominant urgency incontinence were excluded. For patients with mixed type of incontinence, the operation has a positive effect on the urgency component [10].

Due to the low prevalence of groin or vaginal pain, tape protrusion, dyspareunia, voiding and postmicturition symptoms, it was impossible to prove a statistically significant effect on the IQOL. We were also unable to assess the change in the quality of life for re-operations, due to the small number of cases. The occurrence of complications did not depend on the type of surgical procedure.

Further long-term monitoring of the development trends in the success rate of anti-incontinence operations is needed to take into account the occurrence of complications and quality of life, as well as an overall assessment of the success rate of the new surgical procedures [29]. It is important to focus not only on the frequency of individual symptoms, but also on their development over time. The occurrence of complications shows a dynamic development over time, and its effect on the IQOL after the operation is significant.

The main limitation of this study is the non-randomization of the type of surgical procedure. Another issue is the lack of studies dealing with long-term follow-up of the quality of life after anti-incontinence operations as their main objective. The situation is further complicated by the number of different questionnaires, where use of a specific type of HRQoL (Health Related Quality of Life) questionnaire is not directed. This means that studies are often not comparable because they use different HRQoL questionnaires and methodology.

## CONCLUSIONS

Anti-incontinence operations significantly improve quality of life in the long-term follow-up.



The resulting effect of the 3 monitored operations is comparable. We observed constantly high subjective satisfaction for Burch colposuspension, though less with TVT and TVTO.

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