RESULTS

The study enrolled 30 patients recruited from gynecology outpatient clinic of Benha University Hospitals.

I- Sociodemographic characters (Table 2):

The ages of the study group (30 patients) ranged between 20-53 years with an average age of 39.9 ± 9. Twenty patients (66.7%) aged between 20 – 40 years and 10 patients (33.3%) aged between 41-53 years. Six patients were menopausal for a mean duration of 4.5 ± 2.26 years (rang between 2-8 years).

In our study we studied the effect of patients age on the outcome of surgery and we found no significant difference (P > 0.05) between the age groups as regard the outcome of surgery.

The patients had childbirth ranged between 2-5, with a mean parity of 3.17 ± 0.98.

The mean body mass index (BMI) was 30.14 ± 3.04 and ranged between 23.50 ± 34.89. Twenty one patients (70%) of our study were obese (BMI ≥ 30) while 9 patients (30%) were non-obese (BMI ≤ 29), obesity was defined as BMI > 30 according to ***Mukherjee & Constantine, (2001).***

All our patients were complaining of GSI for an average duration of 27 ± 8.89 months, and the range was from 12 to 55 months.

Table (2): Showing the sociodemographic characters of the study group:

Parameter	Range		Mean	± SD
	Min.	Max.		
Age (year)	20	53	39.9	9
Parity	2	5	3.17	0.98
Weight (kg).	60	90	77.9	7.6
Height (cm)	155	170	162	3.54
BMI	23.50	34.89	30.14	3.04
SUI duration (month)	12	55	27	8.89

Table (3): shows a descriptive analysis of the sociodemographic characters of successful and improved groups. The data could not be compared statistically due to small sample size of the improved group among the study group (n. = 2).

Table (3): showing the sociodemographic characters of successful and improved groups:

Parameter	Successful (no. = 28)	Improved group (No. 2)
	Mea ± SD	Mea ± SD
Age (year)	39.82 ± 8.04	40.0 ± 2.3
Parity	3.18 ± 0.99	3 ± 1.41
Weight (kg.)	79.1 ± 7.71	71.2 ± 2.09
Height (cm.)	162 ± 3.63	162 ± 2.83
BMI	30.34 ± 5.79	27.24 ± 0.14
SUI duration (month)	26.14 ± 8.19	39 ± 12.73

Table (4): Showing the effect of patient's age on the success of surgery.

Outcomes of surgery	Age group (25-40y) (no =20)		Age group (41- 53 year) (no. =10)		Z	P	Sig.
	No.	%	No.	%			
Successful cases	19	95%	9	90%	0.47	P > 0.05	N.S.

Test of significant (P. value): Z test (Test of proportion).
S. Significant
N.S. : Non significant

Table (5): Showing the distribution of studied patients according to obesity.

Parameter	**Studied patients (no. = 30)**	
Non- obese (BMI $\leq$ 29)	9	3
Obese (BMI $\geq$ 30)	21	70 %

Table (6): Showing the distribution of obesity among successful and improved groups:

Parameter	**Successful group (no. 28)**		**Improved group (no. = 2)**	
Non-obese (BM $\leq$ 29)	7	25	2	100%
Obese (IBM $\geq$ 30)	21	75	0	0%

II- Pre-operative subjective and objective data (Tables 7, 8):

Table (7): showing pre-operative descriptive analysis of subjective and objective data of the study groups.

Subjective and objectives data	Study group (no. = 30) Mean ± SD or %		
Subjective number of leaks/day	Range	3 –12	
	Mean ± SD	6.4 ± 2.74	
Number of pads/day	Range	2- 9	
	Mean ± SD	4.42 ± 1.62	
Grade of cystocele	No cystocele	3	10%
	1	16	53.3%
	2	11	37.7%
	3	0%	
	4	0%	
Grade of severity of GSI	I	60	
	II	30	
	III	10	

Table (8): Showing pre-operative descriptive analysis of subjective and objectives data of successful and improved groups:

Subjective and objective data	Successful group (no. 28) Mean ± SD or %		Improved group (no=2) mean ± SD or %
Subjective number of leaks/day	6.02 ± 2.46		13 ± 1.4
Number of pads/day	4.13 ± 124		8.4 ± 0.7
Grade of cystocele	No cystocele	10%	0%
	1	53.3%	100%
	2	37.7%	0%
	3	0%	0%
	4	0%	0%
Grade of severity of GSI	I	64.3%	0%
	II	32.1%	0%
	III	3.6%	0%

III- Pre-operative urodynamic studies (Tables 9, 10): it includes:

a- Subtracted cystometry :

- Volume infused at first sensation (FSV inf.).
- Pressure detrusor at first senastion (FSP det.).
- Volume infused at intense desire (IDV inf.).
- Pressure detrusor at intense desire (IDP det.).
- Volume infused at maximum cystometric capacity (MCCV inf.).
- Pressure detrusor at maximum cystometric capacity (MCCP det.).

b- Post-voiding residual volume:

Table (9): Showing pre-operative analysis of urodynamic studies of the study group :

Pre-operative urodynamic parameter	**Study group (no. = 30)**			
	Range		Mean	± SD
	Min.	Max.		
FSV	100	180	138.2	21.73
FSP	0	6	1.8	4.28
IDV	260	430	350.8	40.88
IDP	0	8	5.9	1.70
MCCV	380	620	500	53.8
MCCP	6	15	8.7	1.68
Post-void residual volume	10	50	14.1	9.32

Volume in ml, pressure in cm H_2O.

Table (10): Shows the pre-operative urodynamic data of successful and improved groups. The data could not be compared statistically due to small sample size of the improved group among the study group (no. 2).

Table (10): showing pro-operative analysis of urodyamic studies for successful and improved groups.

Pre-operative urodynamic parameter	Successful group (no.= 28)	Improved group (no. = 2).
	Mean ± SD	Mean ± SD
FSV inf.	140.2 ± 24.69	110 ± 14.14
FSP det.	1.8 ± 2.10	3 ± 1.41
IDV inf.	354.5 ± 42.24	300 ± 14.14
IDP det.	5.8 ± 1.70	7.5 ± 0.71
MCCV inf.	500 ± 55.2	470 ± 7.06
MCCP det.	8.4 ± 1.63	9.4 ± 1.84
Post-void residual volume	14.7 ± 9.27	7.4 ± 10.6

Volume in ml, pressure in cm H_2O.

IV. Operative and post-operative data (Tables 11,12):

1- Operative time:

The mean operative time for TOT procedure in our study was 28.5± 5.6 minutes, and the range between 15 - 45 minutes.

2- Operative blood loss :

The operative blood loss in our study was minimal with a mean of 55 ± 17.76 ml and the range between 40- 100ml.

3- Ambulation:

As TOT is a minimally invasive procedure, so immediate ambulation was easy with a mean of 3.3 ± 1.12 hours and the range between 1-6 hours.

4- Post- operative catheter duration:

No catheters were left in our patients after TOT procedure.

5- Post-voiding residual volume before patient discharge:

The mean post-voiding residual volume was 20.25 ± 10.35ml, and the range between 10-50 ml.

6- Duration of hospital stay:

The mean duration of hospital stay in our study was short (24.5 ± 14.85 hours) about 1/2 day, and the range between 12-48 hours.

Table (11): Showing analysis of operative and postoperative data in the study group:

Parameter	Study group (no. =30)			
	Range		Mean	± SD
	Min	Max		
Operative time (minute)	15	45	28.5	5.6
Operative blood loss (ml).	40	100	55	17.76
Ambulation (hour)	1	6	3.3	1.12
Post-operative catheter duration (day)	0	0	0	0
Post-voided residual volume (ml)	10	50	20.25	10.35
Duration of hospital stay (hour)	24	48	24.5	14.85

Table (12) shows the operative and post-operative data of successful and improved groups. The data could not be compared statistically due to small sample size of the improved group among the study group (no = 2).

Table (12): Showing operative and postoperative data of successful and improved groups:

Parameter	Successful group (n. =28)	Improved group (n. = 2)
	Mean ± SD	**Mean ± SD**
Operative time (minute)	26.5±8.46	27.2±3.53
Operative blood loss (ml).	55.35±18.12	50±32.02
Ambulation (hour)	3.3±1.16	3.5±0.71
Post-operative catheter duration (day)	0±0	0±0
Post-voided residual volume (ml)	16.24±9.08	12.4±5.58
Duration of hospital stay (hour)	34.5 ± 18.78	33 ± 2.82

V- Operative and post- operative complication:

1- Operative complications:

a- Bladder injury: No Bladder injury.

b- Urethral injury : No urethral injury occurred.

2- Postoperative complications:

Short-term complications :

a- Local haematoma:

In our study local haematoatoma not occurred.

b- Urine retension and voiding difficulty :

In our study 30 patients (100%) were able to micturate spontaneoulsy within 3-4 hours after TOT procedure with insignificant post-voided resiual volume.

c- Significant post-operative pain:

In our study, postoperative pain was minimal in all patients, and just non-steroidal anti-inflammatory drugs were given when needed.

d- Local wound infection:

No local wound infection occurred in any patients of our study as the incisions were small and dissection was minimal.

e- Urinary tract infection:

In our study, 1 patients (3.3%) developed post-operative urinary tract infection.

ii- Long-term compilations:

a- De-novo detrusor instability & denovourge incontinence:

None of our patients developed de-novo detrusor instability or denovo urge inconinence complained by .

b- Defective healing & tape rejection:

There was no defective healing or tape rejection in all our patients of TOT after 12 months follow- up indicating that the polypropylene mesh used is an inert, tolerable material.

VI- Pre-operative versus post-operative subjective and objective Data (Table 13 & 14):

We can find that there is a marked improvement in the number of leaks, number of pads, in our study with high significant difference (P< 0.01) between pre-operative and 2nd month postoperative data and between preoperative and 6th month postoperative data and between preoperative and 12th month postoperative data.

On comparing the 2nd month and 6th and 12th months post-operative data as regards the above mentioned parameters there was nearly no change with no significant difference (p > 0.05). this means that longer term follow-up showed n odeterioration in the cured cases and no improvement in the improved cases.

As TOT does not cure cystocele, so patients with grade 1 cystocele persisted with cystoceles, so, we did not attempt to treat it surgically. Also, we preferred not to do anterior repair so that not to interfere with the results of the TOT in our study.

On comparing, 2nd, 6th, & 12th months postoperative data with the preoperative data regarding the grade of severity of GSI, there was a highly significant different (p < 0.01) as regard grade I & II and there was no statistically significant different (p > 0.05) as regard III.

On the other hand, there was no statistically significant difference (P > 0.05) on comparing the 2nd, 6th and 12th months follow-up data regarding the grads of severity of stress urinary incontinence denoting that there is no deterioration in the cured or improved cases.

Table (14): Shows, the post-operative subjective and objective data of successful and improve groups. The data could not be compared statistically due to small sample size of the improved group among the study group (no. = 2).

Table (13): Showing the comparison between post-operative subjective and objective data of successful and improved groups:

Post operative subjective and objective data		Successful group (no = 28)	Improved group (no. =2)
		Mean SD or %	Mean SD or %
Subjective number of leaks/day	2nd month	0.04 ± 0.19	11 ± 1.4
	6th month	0.04 ± 0.19	11 ± 1.4
	12th month	0.04 ± 0.19	13 ± 1.4
Number of pads/days	2nd month	0.04 ± 0.19	8.4 ± 0.7
	6th month	0.04 ± 0.19	9.5 ± 0.7
	12th month	0.04 ± 0.19	9.5 ± 0.7
Grade of cystocele	No cystocel	10%	0%
	1	53.3%	100%
	2	37.3%	0%
	3	0%	0%
	4	0%	0%
Grade of severity of GSI	NO GSI	96.4%	0%
	I	3.6%	0%
	II	0%	0%
	III	0%	100%

Table (14): Showing pre-operative versus post-operative and objective data in the study group:

Subjective and objective data		Pre-op. Mean ± SD or %	Post-op 2nd month Mean ± SD or %	Post-op 6th month Mean ± SD or %	Post. Op. 12th month mean ± SD or %
Subjective no. of leaks/day		6.4 ± 2.74	0.77 ± 2.80	0.83 ± 3.04	0.9 ± 3.30
Number of pads/day		4.42 ± 1.62	0.6 ± 2.16	0.7 ± 2.53	0.7 ± 2.53
Gratde of cystocele	No. cystocele	10%	30	30	30
	1	53.3%	70%	70%	70%
	2	37.7%	0%	0%	0%
	3	0%	0%	0%	0%
	4	0%	0%	0%	0%
Grade of severity of GSI	No SUI	0%	90%	90%	90%
	I	60%	3.3%	3.3%	3.3%
	II	30%	0%	0%	0%
	III	10%	6.7%	6.7 %	6.7%

Table (15): Showing p value pre-operative versus post-operative objective data in the study groups.

P value pre- Vs post 2^{nd} m	P value pre Vs post 6^{th} m	P value pre Vs post 12^{th} m	P value pre 2^{nd} m Vs post 6^{th} m	P value pre 2^{nd} m Vs post 12^{th} m
P < 0.01 H.S.	P < 0.01 H.S.	P < 0.01 H.S.	P > 0.05 N.S.	P > 0.05 N.S.
P < 0.01 H.S.	P < 0.01 H.S.	P < 0.01 H.S.	P > 0.05 N.S.	P > 0.05 N.S.
P > 0.05 N.S.	P > 0.05 N.S.	P > 0.05 N.S.	P > 0.05 N.S.	P > 0.05 N.S.
P > 0.05 N.S.	P > 0.05 N.S.	P > 0.05 N.S.	P > 0.05 N.S.	P > 0.05 N.S.
-	-	-	-	-
-	-	-	-	-
-	-	-	-	-
P < 0.01 H.S.	P < 0.01 H.S.	P < 0.01 H.S.	P > 0.05 N.S.	P > 0.05 N.S.
P < 0.01 H.S.	P < 0.01 H.S.	P < 0.01 H.S.	P > 0.05 N.S.	P > 0.05 N.S.
P < 0.01 H.S.	P < 0.01 H.S.	P < 0.01 H.S.	P > 0.05 N.S.	P > 0.05 N.S.
P < 0.05 N.S.	P < 0.05 N.S.	P < 0.01 N.S.	P > 0.05 N.S.	P > 0.05 N.S.

Test of significance (P. Value): Paired *t* test N.S. Non significant

Z- test H.S. Highly significant

VII- Post- operative Urodynamic studies (table 16, 17, 18):

Table (16): Showing 2nd month post-operative analysis of urodynamic data in the study groups:

Parameter	Study group (no. =30)			
	Range		Mean	± SD
	Min	Max		
FSV inf.	110	180	136.7	17.63
FSP det.	0	8	1.9	2.23
IDV inf.	300	450	354.8	44.05
IDP det.	0	10	5.7	2.53
MCCV inf.	400	620	508.3	51.67
MCCP det.	6	12	8.3	1.14
Post-voidded residual volume	5	20	6.4	7.08

Volume in ml., pressure in cm H_2O

Table (17): Showing 2nd month post-operative analysis of urodynamic data of successful and improved groups;

Parameter	Successful group (no.= 28)	Improved group (no. = 2).
	Mean ± SD	Mean ± SD
FSV inf.	140.3 ± 17.6	110 ± 19.9
FSP det.	1.7±2.14	5±1.41
IDV inf.	358.03±43.33	310±14.14
IDP det.	5.7±2.34	6.5±2.12
MCCV inf.	510±55.48	485±21.21
MCCP det.	8.3±1.60	9±1.41
Post-void residual volume	6.24±6.67	10±7.06

Volume in ml., pressure in cm H_2O

VIII. Comparison between pre-operative and 2nd month post-operative urodynamic studies (Table 18):

a- Subtracted cystometry:

There was non-significant change ($p > 0.05$) in all cystometrical parameters, on comparing 2nd month postoperative values with the preoperative one. This mean that TOT pocedure does not affect the bladder capacity. On the other hand examination of subtracted cystometry data for each patient, none of our patients developed de-novo detrusor instability or de-novo urge incontinece 2 month postoperatively.

b- Post-voiding residual volume:

Regarding the post-voiding residual volume. There was significant decreases post-operative ($P < 0.05$) in the post-voiding residual volume from 14.3 ± 9.35 ml to 6.5 ± 70.9ml. This mean that there was no obstructive side effect to the TOT procedure.

Table (18): Showing comparison between pre-operative and 2nd month post-operative urodynamic data in the study groups:

Uradynamic data	Pre-operative	2nd month post-operative	t	p	Sign.
FSV inf.	138.2±21.73	136.7±17.63	0.19	P> 0.05	N.S.
FSP det.	1.8±4.28	1.9±2.23	0.08	P> 0.05	N.S.
IDV inf.	350.8±40.88	354.8±44.05	0.26	P> 0.05	N.S.
IDP det.	5.9±1.70	5.7±2.53	0.26	P> 0.05	N.S.
MCCV inf.	500±53.8	508.3±51.67	0.28	P> 0.05	N.S.
MCCP det.	8.7±1.68	8.3±1.14	0.55	P> 0.05	N.S.
Post-void residual volume	14.1 ± 9.32	6.4±7.08	2.60	P< 0.05	S

Volume in ml., pressure in Cm H2O. N.S.;: non significant
Test of significant (P. value): paired t test S= significant