RESULTS

A Total number of 60 patients complaining of stress urinary incontinence were included in this study as they completed the follow up period of 1 year . They were randomly divided into two groups :

- **Group I :** Thirty patients were candidate for TVT-Secur.
- **Group II :** Thirty patients were candidate for facial patch sling.

Table (1) Baseline characteristics of the studied groups.

Group / Variable	**TVT secure (N=30)**		**Facial sling (N=30)**		St. "t"	p
	Mean ± SD	Range	Mean±SD	Range		
Age (years)	42.07 ± 10.08	24-61	43.3 ± 10.4	25-62	-0.48	>0.05
Parity	4.9±1.9	2-8	5.4±2.1	1-9	-0.97	>0.05
Vaginal delivery	4.2±2.2	1-8	4.8±2.3	1-9	-0.91	>0.05
C.S.	0.63±0.99	0-4	0.60±1.0	0-4	0.13	>0.05
Duration of SUI (in years)	3.1±1.29	1-6	4.07±2.03	1-9	-2.2	<0.05*

The age of the patient in group I ranged from 24-61 years ; with an average of 42.07 ± 10.08.The age of the patients in group II ranged from 25-62 years ; with an average of 43.3 ± 10.4 years.

This Table showed that there was insignificant difference between the studied group regarding the age (P value > 0.05)

The mean number of vaginal deliveries in Group I was 3.9 ± 2.1 with a range of 1-8 deliveries, whereas the mean number of vaginal deliveries in group II was 4.03 ± 2.5 with a range of 1-9 deliveries.

The range of caesarian section (CS) in group I was 0-2 and 0-1 in group II.

The mean number of Parity in group I was 4.3 ± 2.32 with a range of 1-8 where as the mean number of parity in group II was 4.5 ± 2.53 with a range of 1-9 .

This table showed that there was insignificant difference between the studied groups regarding parity and the mode of delivery (p value > 0.05).

This table showed that there was statistically significant difference regarding the duration of preoperative S.U.I in both groups (P value < 0.05)

A-Preoperative evaluation :

The severity of SUI was evaluated clinically by using stamey's grading system where:

Grade 1: Leakage only with sever stress such as coughing or laughing.

Grade II: Leakage with moderate activity such as walking or running

Grade III: Total urinary incontinence without relation to physical activity ***(Stamey, 1992).***

Grade I was detected in 18 case in group I (60%) and 13 cases in group II (43.3%) while 12 cases in group I (40%) and 15 cases in group II (50%) classified as grade II SUI and 0 cases in group I (0%) and 2 cases in group II (6.7%) classified as grade III SUI according to stamy's grading system ***(Table 2).***

Table (2): *Grades of SUI according to stamy's grading system*.

Grade			group		Z	P
			TVT secure	Facial sling		
	grade I	Count	18	13	1.3	>0.05
		% within group	60.0%	43.3%		
	grade II	Count	12	15	-0.78	>0.05
		% within group	40.0%	50.0%		
	Grade III	Count	0	2	-1.44	>0.05
		% within group	.0%	6.7%		
Total		Count	30	30		
		% within group	100.0%	100.0%		

This table shows that there was statistically insignificant difference between the two groups regarding the grade of SUI (P value >0.05)

B- Preoperative clinical parameters*:*

Post menopausal state was found in 12 patients (40%) in group I and 13 Patients (43.3%) in group II. It was statistically insignificant (P value >0.05) **(table 3).**

table (3) Distribution of the studied groups according to menopausal state.

Menopause			group		
			TVTsecure	Facial sling	Total
	Premenopausal	Count	18	17	35
		% within group	60.0%	56.7%	58.3%
	Postmenopausal	Count	12	13	25
		% within group	40.0%	43.3%	41.7%
Total		Count	30	30	60
		% within group	100.0%	100.0%	100.0%

X^2 = 0.07 **P >0.05**

C) preoperative urodynamic evaluation includes:

- Free flowmetry with estimation of post voiding residual urine
- Cystometry with estimation of valsalva leak point pressure (VLPP).
- Pressure flow study (PFS)
- Patients were categorized preoperatively according to valsalva leak point pressure into 3 groups :

1- Patients with VLPP ≥ 90 Cm H_2O type I SUI .

2- Patients with VLPP≥ 60 < 90 Cm H_2O type II SUI.

3- Patients with VLPP < 60 Cm H_2O (intrinsic sphincter deficiency) ***(table 4).***

Table (4) **The preoperative VL PP in the studied groups.**

VLPP (Cm H_2O)		group		Z	P
		TVT secure	Facial sling		
<60	Count	1	3	-01.04	>0.05
	% within group	3.3%	10.0%		
60- 90	Count	20	20	0.0	>0.05
	% within group	66.7%	66.7%		
≥90	Count	9	7	0.58	>0.05
	% within group	30.0%	23.3%		
Total	Count	30	30		
	% within group	100.0%	100.0%		

This table shows that there was statistically insignificant difference between the studied groups regarding VLPP (P value > 0.05).

D) Operative evaluation :

Operative evaluation included the operative time in minutes, Intra operative bleeding and any other intra operative complication which can occur in both studied groups. We had 3 cases of iatrogenic bladder perforation in group II which were recognized and managed intra operatively. Also we had 3 cases of urethral injury in group I and also repaired and urethral catheter left for 10 days with no fistula after catheter removal.

Table (5)Distribution of the studied groups according to operative time , blood loss and postoperative stay.

Group / Variable	**TVT secure (N=30)**		**Facial sling (N=30)**		"t"	P
	Mean ± SD	Range	Mean ± SD	Range		
Operative time	13.7±2.32	10-20	52.2±7.16	40-65	-28.1	<0.001*
Blood loss (ml)	69±9.7	50-100	117.5±24.5	85-160	-10.1	<0.001*
Postoperative stay	1.26±0.45	1-2	1.46±0.86	1-4	-1.13	>0.05

This table showed that there was highly statistical significant difference between studied groups regarding operative time (P value < 0.001) but not the post operative hospital stay (p value >0.05) .

This table also showed that there was highly significant statistical difference between the studied groups regarding intra operative blood loss.

Table (6) Distribution of the studied groups according to intra-operative complications.

Group / Variable	TVT secure (N=30)		Facial sling (N=30)		"Z"	P
	no	%	no	%		
Bladder perforation	0	0.0	3	10	-1.78	<0.05*
Urethral injury	3	10.0	0	0.0	1.78	<0.05*

This table showed that there was significant statistical difference between the studied groups regarding intra operative complications .

E) Early post operative complication :

The early postoperative complication occurred in our research was studied in both groups. We had 4 cases of urine retention in group II (13.3%) and no cases in group I with statistically significant difference between both groups (P value < 0.05) .All cases were managed by urethral catheterization for maximum 1 week duration and all cases were improved .

The incidence of post operative urinary tract infection (UTI) was 10% (3cases) in group I and 20 % (6 cases) with insignificant statistical difference between both groups and all cases were treated medically according to culture and sensitivity ***(table 7).***

Table (7) Early post-operative complications in the studied groups

Group / Variable	TVT secure (N=30)		Facial sling (N=30)		"Z"	p
	no	%	no	%		
UTI	3	10.0	6	20.0	-1.09	>0.05
Retention	0	0.0	4	13.3	-2.07	<0.05*

F- Late postoperative complications:

Urethral erosion occurred in one case in group I and not occurred in group II .This case was recognized 2 months postoperatively as she still incontinent . This patient was managed by urethral mobilization and tape extracted and then facial patch sling using rectus sheath patch was done then the patient was continent.

Dyspareunia occurred in 1 case (3.3%) in group I and in 3 cases (10%) in group II with statistically insignificant difference between both groups (***table 8***)

Table (8) Late post-operative complications in the studied groups

Group / Variable	**TVT secure (N=30)**		**Facial sling (N=30)**		"Z"	p
	no	%	no	%		
Urethral erosion	1	3.3	0	0.0	1.01	>0.05
Dysparunia	1	3.3	3	10.0	-1.04	>0.05

G- Post-operative cure rate:

The cure rate in our study was evaluated objectively and subjectively. Patients were considered cured if they did not report any episodes of urine leakage, ceased to wear any incontinence protection, and had a negative cough test. If a patient reported maintenance of SUI or a positive cough test, but the number of incontinence protections necessary decreased by >50% and she answered affirmatively to the question ‘‘Are you satisfied with the result of the surgery?, the patient was considered improved. All other cases were deemed failures.

In group I the cure rate was 80% and in group II the cure rate was 90%. In group I the improvement was 16.7% and in group II the improvement was 6.7% while failure was detected in one patient (3.3%) in group I as this patient had VLPP <60 Cm H_2O and the same failure rate was found in group II. These were statistically insignificant differences regarding the cure, improvement and failure rate in both groups ***(table 9).***

Table (9) Distribution of the studied groups according to outcome.

Group / Outcome	**TVT secure (N=30)**		**Facial sling (N=30)**		"Z"	P
	no	%	no	%		
Cured	24	80.0	27	90.0	-1.09	>0.05
Improved	5	16.7	2	6.7	1.21	>0.05
Failed	1	3.3	1	3.3	----	----

Post- operative follow up

All patients were followed postoperatively by history taking, physical examination, measurement of post-voiding residual and free flow.

The preoperative maximum flow rate (Q_{max}) was determined in each group in free flow and were found to be 24.7 $\pm$ 1.2 in group I and 25.6 $\pm$ 1.7 in group II with statistically significant difference in both groups preoperatively (P value <0.05).

On the other hand, there was no statistically significant difference between the 2 groups regarding the postoperative Q_{max} (P value > 0.05).

Regarding group I the pre-operative Q_{max} was 24.7 ± 1.2 and post-operative was 21.3 ± 0.78 . There is highly significant difference (paired t = 18.8, P value < 0.001) . in group II mean pre & post –operative Q_{max} was 25.6 ± 1.7& 20.9 ± 0.67 respectively .

This difference was also highly significant (paired t = 15.5 , P value < 0.001) . ***(table 10).***

Table (10) Distribution of the studied groups according to Q_{max}.

Group / Q max	**TVT secure (N=30)**		**Facial sling (N=30)**		St. "t"	p
	Mean	SD	Mean	SD		
Preop. Q_{max}	24.7	1.2	25.6	1.7	-2.4	<0.05*
Postop. Q_{max}	21.3	0.78	20.9	0.67	1.59	>0.05
Paired "t" P	18.8 <0.001*		15.5 <0.001*			

Table (11) Distribution of the studied groups according to residual urine

Group / Residual urine	**TVT secure (N=30)**		**Facial sling (N=30)**		St. "t"	P
	Mean	SD	Mean	SD		
Preop. Residual urine	26.1	2.9	25.4	2.4	1.12	>0.05
Postop. Residual urine	26.9	2.5	26.5	2.3	2.3	<0.05*
Paired "t" P	-1.97 >0.05		-0.96 >0.05			

This table shows that the preoperative voiding residual urine was statistically insignificant in both groups. On the other hand the postoperative voiding residual urine was statistically significant in comparison of both groups (p value <0.05)