RESULTS

The study enrolled 60 patients recruited from urology and gynecology outpatient clinics of Benha Faculty of Medicine; they were randomly divided into two groups:

- **Group I:** Thirty patients were candidate for TVT.
- **Group II:** Thirty patients were candidate for modified fascial patch sling.

The age of the study group I ranged from 20 to 53 years, with an average of 39.2 ± 9 years. Fourteen patients aged from 20 to 40 years, whereas 16 patients were aged from 41 to 53 years, whereas only 5 patients were aged from 51 to 53 years old.

The age of the study group II ranged from 24 to 54 years, with an average of 40.2±8.9 years. Fifteen patients aged from 20 to 40 years, whereas the other 15 patient were aged from 41 to 54 years.

The mean parity of group I was 4 ± 2.2 with arange of 1–12 whereas the mean parity of group II was 4.6 ± 2.5 with arange of 1–11 deliveries. The mean vaginal delivaries in group I was 3.9 ± 2.2 with arange of 1–12 whereas the mean vaginal delivaries in group 2 was 4.5 ± 2.8 with arange of 0–11 deliveries. The range of caesarian section (CS) in group I was 0–1 and from 0–2 in group II (Table 3).

Table (3): Age, parity, vaginal delivery and cesarean section in the studied groups.

Parameter	*Group*	*Mean ± SD*	*Range*	*t*	*P value*
Age	Group I	39.2±9	20 - 53	0.4	>0.05
	Group II	40.2±8.9	24 - 54		
Parity	Group I	4 ± 2.2	1 - 12	1	>0.05
	Group II	4.6 ± 2.5	1 - 11		
Vaginal delivery	Group I	3.9 ± 2.2	1 - 12	0.9	>0.05
	Group II	4.5 ± 2.8	0 - 11		
CS	Group I	0.06 ± 0.3	0 - 1	0.7	>0.05
	Group II	0.1 ± 0.4	0 - 2		

CS: Caesarian section.

This table showed that there was insignificant difference between the studied groups regarding age, parity, the mode of delivary (P value > 0.05).

Associated preoperative urinary tract infection was presented in 4 cases in group I and 5 cases in group II and was treated according to culture and sensitivity before surgery.

A- Preoperative evaluation:

The severity of SUI was evaluated clinically by using Stamey's grading system. Where:

Grade I: Leakage only with severe 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

Grade I SUI was detected in 14 cases in group I and 21 cases in group II, while 13 cases in group I and 14 cases in group II classified as grade II SUI and 3 cases in group I and 4 cases in group II classified as grade III SUI according to Stamey's grading system. The 7 cases with grade III SUI had VLLP <60 cm H_2O (Table 4 and Fig. 46).

Table (4): The preoperative grade of SUI in the studied groups.

Grade	Group	
	Group I	Group II
Grade I	14 (46.7%)	12 (40%)
Grade II	13 (43.3%)	14 (46.7%)
Grade III	3 (10%)	4 (13.3%)
Total	30	30

This table shows that there was insignificant difference between the two groups regarding the grade of SUI (Chi square 1.3 and P value >0.05).

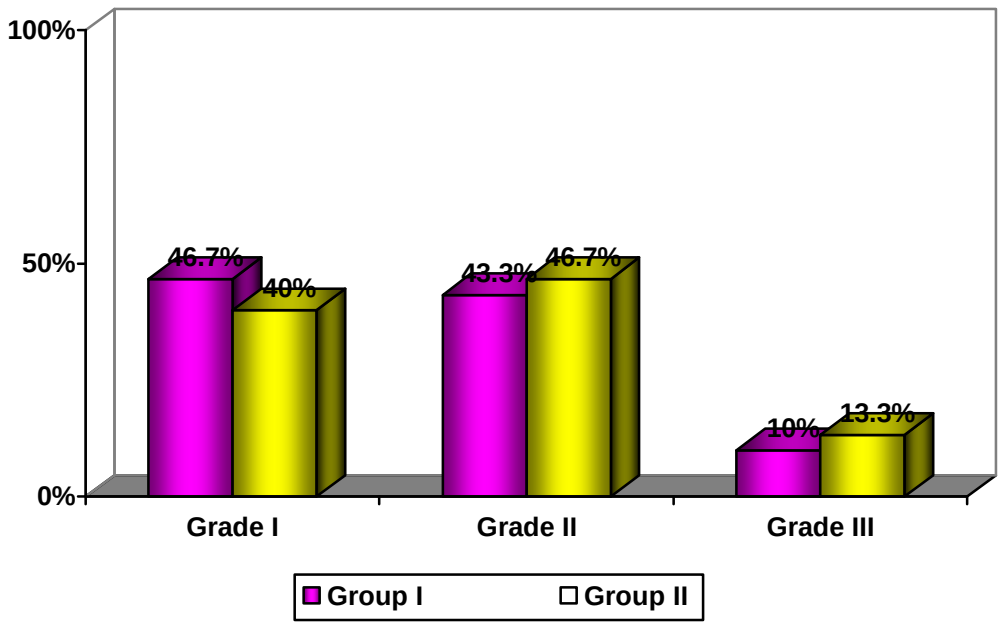


Fig. (46): The preoperative grade of SUI in the studied groups.

Bladder base prolapse (cystocele) was classified according to **Baden and Waker** classification where:

Grade I: Minimal bladder descent towards the introitus with straining.

Grade II: Bladder descents up to introitus with straining.

We had 12 cases in group I and 16 cases in group II classified as grade I cystocele, 17 cases in group I and 11 cases in group II classified as grade II cystocele and one case in group I and 3 cases in group II without cystocele (Table 5 and Fig. 47).

Table (5): The preoperative cystocele grade in the studied groups.

Cystocele grade	***Group***	
	Group I	***Group II***
No cystocele	1 (3.3%)	3 (10%)
Grade I	12 (40%)	16 (53.3%)
Grade II	17 (56.7%)	11 (37.7%)
Total	30	30

This table showed that there was insignificant difference regarding the grade of cystocele in both groups (Chi square 3.2 and P value >0.05).

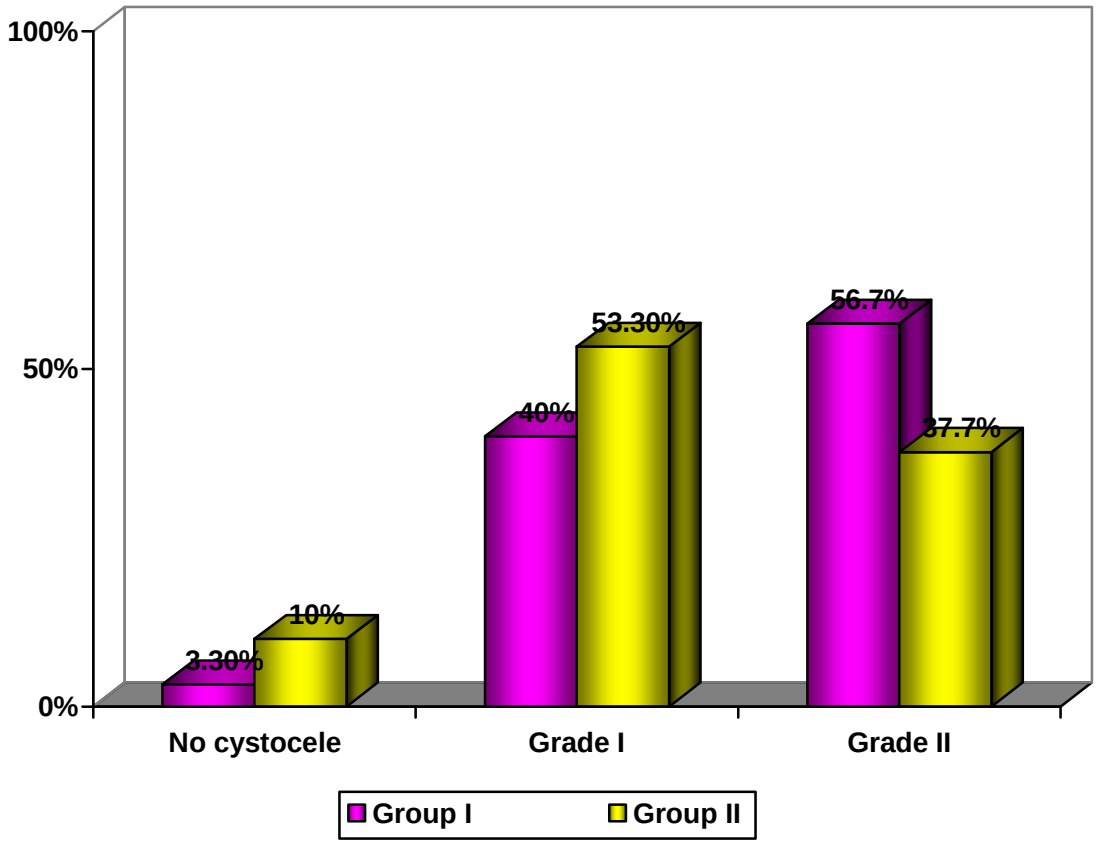


Fig. (47): The preoperative cystocele grade in the studied groups.

The history of previous anti-incontinence surgery was taken in both groups. We had 5 cases in group I with past history of previous anti-incontinence surgery, 4 of them underwent failed colposuspension and the 5th patient underwent failed fascial sling procedure. Four cases in group II underwent failed colposuspension procedure (Table 6).

Table (6): The difference in both groups regarding either primary or had previous anti-incontinence surgery.

SUI	*Group*		*Total*
	Group I	*Group II*	
Primary	25 (83.3%)	26 (86.7%)	51 (85%)
Previous anti-incontinence surgery	5 (16.7%)	4 (13.3%)	9 (15%)
Total	30	30	60

This table showed that there was insignificant difference regarding either primary or recurrent cases in both groups (Chi square 0.1 and P value >0.05).

The preoperative urodynamic evaluation includes:

- Free flowmetry (non-invasive flowmetry) with estimation of post-voiding residual.
- Cystometry with estimation of valsalva leak point pressure (VLPP).
- Pressure flow study (PFS).
- Patients were categorized preoperatively according to valsalva leak point pressure into 2 groups (Table 7 and Fig. 48):
- Patients with VLPP $\geq$ 60 cm H_2O.
- Patients with VLPP < 60 cm H_2O

Table (7): The preoperative VLPP in the studied groups.

VLPP	*Group I*	*Group II*	*Total*
≥60 cm H_2O	27 (90%)	26 (86.7%)	53 (76.7%)
<60 cm H_2O	3 (10%)	4 (13.3%)	7 (23.3%)
Total	30	30	60

This table showed that there was insignificant difference regarding the type of SUI in both groups (Chi square 2.1 and P value >0.05).

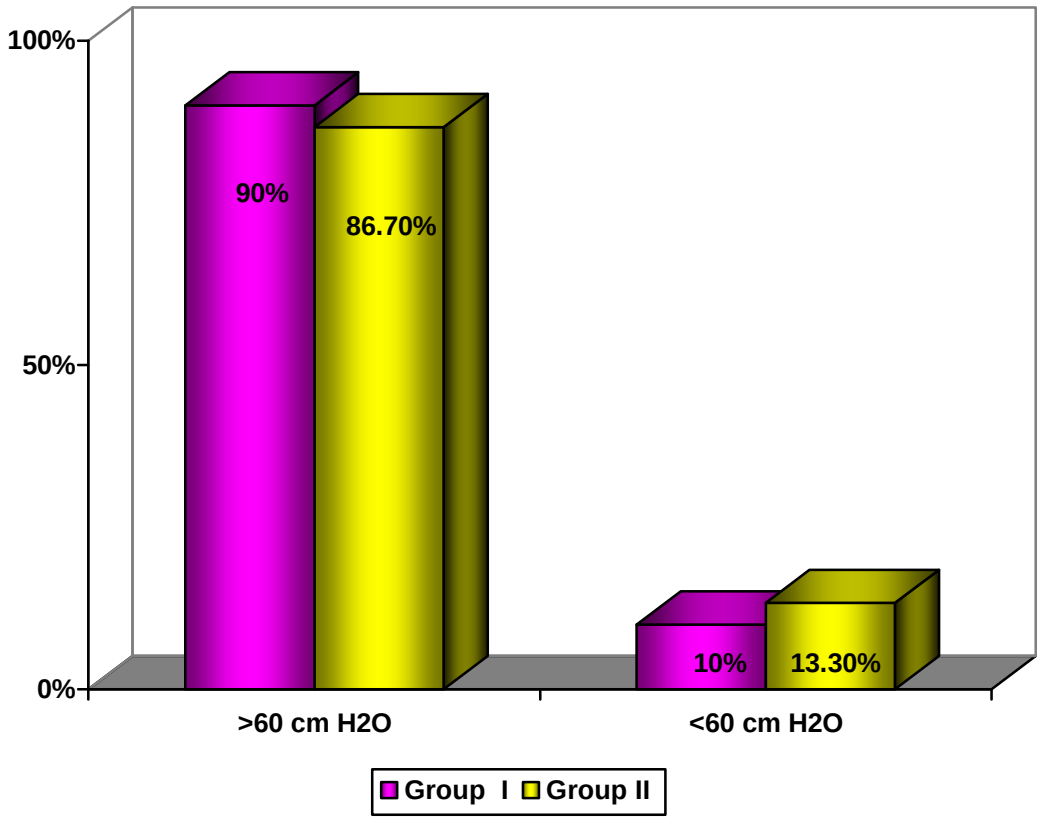


Fig. (48): Showed the preoperative VLPP in the studied groups.

B- 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. Fortunately we had no intra-operative complications except for increased blood loss (>500 cc) in two cases in group II and both of them didn't require blood transfusion and iatrogenic bladder perforation in one case in group II which was recognized and repaired intra-operatively but unfortunately the patient post-operatively showed recurrence of SUI and was managed 4 months later by TVT and the patient was continent after that. The duration of post-operative catheterization and hospital stay were statistically insignificant in both group (Table 8 and Fig.49).

Table (8): The operative time, intra-operative bleeding, duration of catheterization and hospital stay in the studied groups.

Parameter	*Group*	*Mean ± SD*	*Range*	*T*	*P value*
Operative time (min.)	Group I	36.7 ±8.6	25 - 60	21.9	< 0.001**
	Group II	94.4 ±11.6	80 - 120		
Intra-operative bleeding (ml.)	Group I	71.3 ±46.7	30 - 230	6.9	<0.001**
	Group II	264.7 ±146.9	120 - 650		
Duration of catheterization (days)	Group I	2.7 ± 2.5	1-12	1	>0.05
	Group II	2.4 ±2.4	1 - 14		
Hospital stay (days)	Group I	1.2 ±1.1	1 – 5	1	>0.05
	Group II	1.2 ±0.8	1 – 7		

** Highly significant

The previous table showed there were highly statistically significant differences between both groups regarding operative time and intra-operative bleeding (P value <0.001) and statistically insignificant difference between both groups regarding duration of post-operative catheterization and hospital stay (P value > 0.05).

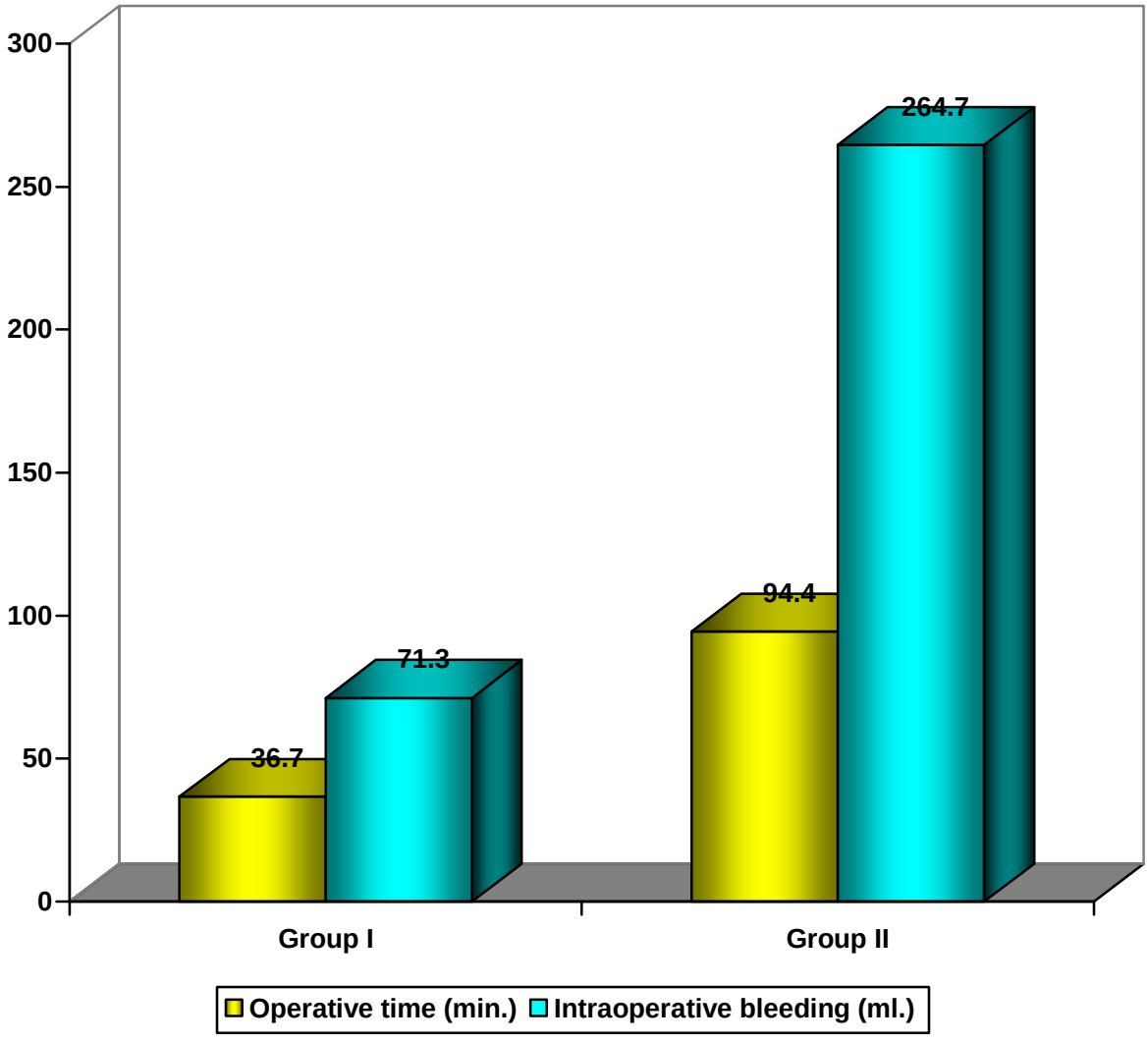


Fig. (49): The mean operative time and intra-operative bleeding in the studied groups.

C- Post-operative complications:

The post-operative complications occurred in our research was studied in both groups. We had 2 cases of urine retention in group I (6.7%) and 3 cases in group II (10%) with statistically insignificant difference between both groups (P value >0.05). All cases were managed by urethral catheterization for maximum 2 weeks duration and all cases were improved.

Post-operative wound infection was found in 1 case (3.3%) in group I (vaginal) and 3 cases (10%) in group II (suprapubic) with statistically insignificant difference between both groups.

The incidence of post-operative urinary tract infection (UTI) was 16.5% (5 cases) in group I and the same in group II, and all cases were treated medically according to culture and sensitivity.

Post-operative denovo urgency was identified in 2 cases (6.7%) in group I and 4 cases (13.3%) in group II and all cases respond to anticholinergic treatment.

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 9 and Fig. 50).

Table (9): The post-operative complications in both groups.

Parameter	*Group*		*P value*
	Group I	*Group II*	
Postop. Retention	2 (6.7%)	3 (10%)	>0.05
Postop. Wound infection	1 (3.3%)	3 (10%)	>0.05
Postop. UTI	5 (16.5%)	5 (16.5%)	>0.05
Denovo urgency	2 (6.7%)	4 (13.3%)	>0.05
Dyspareunia	1 (3.3%)	3 (10%)	>0.05

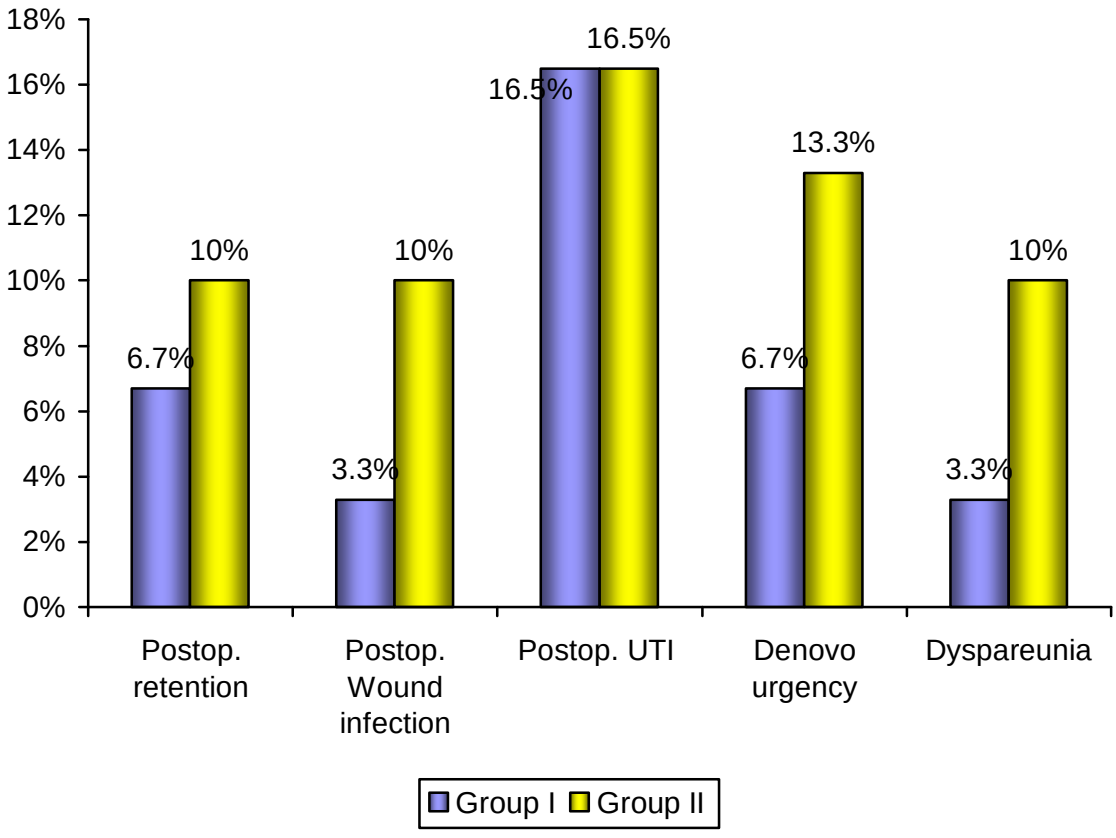


Fig. (50): Post-operative complications in both groups.

The post-operative complications were compared in both groups regarding VLPP and we have found that there was statistically insignificant difference between both groups (Table 10).

Table (10): The post-operative complications in both groups regarding to valsalva leak point pressure.

Parameter	*VLPP*	*Group I*	*Group II*	*P value*
Urine retention	≥ 60	2 (7.4%)	3 (11.5%)	>0.05
	< 60	0 (0%)	0 (0%)	No
Wound infection	≥ 60	1 (3.7%)	1 (3.8%)	>0.05
	< 60	0 (0%)	2 (50%)	>0.05
UTI	≥ 60	4 (14.8%)	3 (11.5%)	>0.05
	< 60	1 (33.3%)	2 (50%)	>0.05
Denovo urgency	≥ 60	2 (7.4%)	3 (11.5%)	>0.05
	< 60	0 (0%)	1 (25%)	>0.05
Dyspareunia	≥ 60	1 (3.7%)	3 (11.5%)	>0.05
	< 60	0 (0%)	0 (0%)	No

D- Post-operative cure rate:

The cure rate in our study was evaluated objectively and subjectively. The patient was considered cured when there no leakage and negative valsalva leak point pressure. In group I the cure rate was 83.4% and in group II the cure rate was 93.4%. The patient was considered improved when she told that there marked decrease in the amount of urine that leak during effort and increase in the activity that induce leakage of urine than it was preoperatively. In group I the improvement

was 6.6% and 3.3% in group II where failure was detected in 10% in group I and 3.3% in group II. There was statistically insignificant difference regarding the cure improvement and failure rate in both groups (Table 11 and Fig. 51).

Table (11): The cure improvement and failure rate in the studied groups.

Parameters	*Group I*	*Group II*	*P value*
Cured	25 (83.4%)	28 (93.4%)	>0.05
Improved	2 (6.6%)	1 (3.3%)	>0.05
Failed	3 (10%)	1 (3.3%)	>0.05

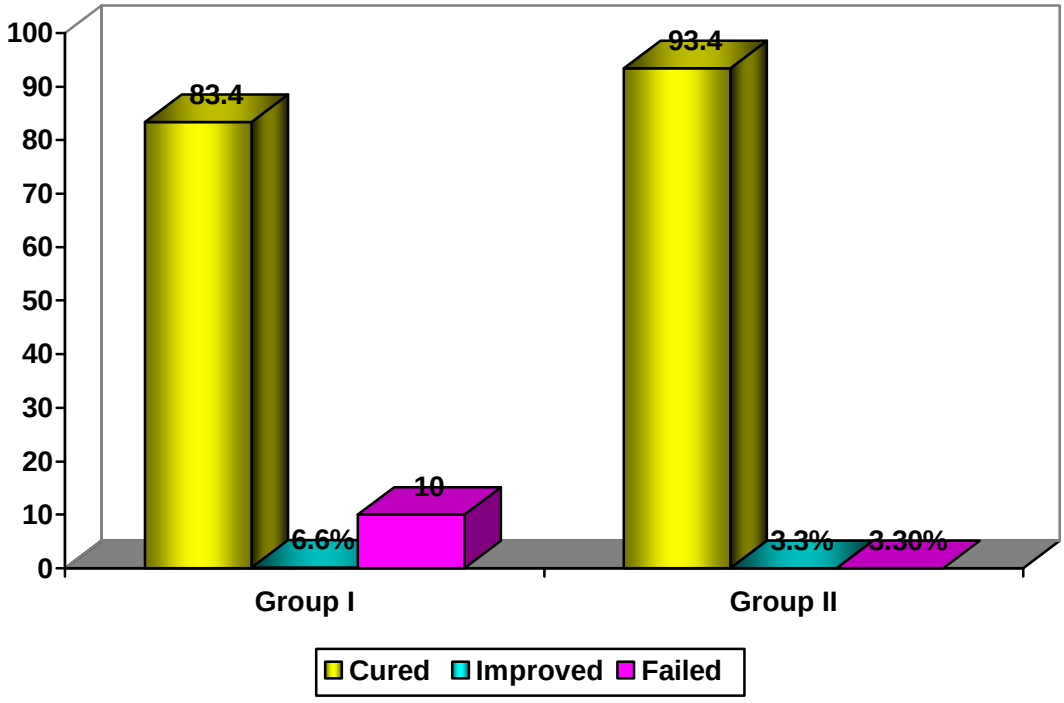


Fig. (51): Success improvement and failure rate in the studied groups.

The impact of age on the cure, improvement and failure of the operative procedure was evaluated and revealed statistically insignificant difference between both groups regarding there age (Table 12).

Table (12): The relation between age on cure, improvement and failed cases in the studied groups.

Parameter	***Age***	***Group I No of pts (%)***	***Group II No of pts (%)***	***P value***
Cured and improved cases	20-40	15 (50%)	13 (43.4%)	>0.05
	40-54	12 (40%)	15 (50%)	>0.05
Failed cases	20-40	2 (6.7%)	1 (3.3%)	>0.05
	41-54	1 (3.3%)	1 (3.3%)	>0.05

The relation between the preoperative grade of SUI and post-operative, cured, improved or failed cases we found statistically significant difference regarding cured and failed cases with grade III SUI, where the cases were failed in group I and succeeded in group II (Table 13).

Table (13): The relation between the preoperative grade of SUI and post-operative cured, improved and failed cases.

Parameter	***Grade of SUI***	***Group I No of pts***	***Group II No of pts***	***P value***
Cured	Grade I	14	12	>0.05
	Grade II	11	12	>0.05
	Grade III	0	4	0.01*
Improved	Grade I	0	0	No
	Grade II	2	1	>0.05
	Grade III	0	0	No
Failed	Grade I	0	1	>0.05
	Grade II	0	0	No
	Grade III	3	0	0.01*

* Significant.

The relation between the preoperative primary or recurrent cases and post-operative cured, improved or failed cases in both groups revealed statistically insignificant difference between both groups (Table 14).

Table (14): The relation between primary or recurrent cases and cured improved and failed cases.

Parameter	***Primary or current***	***Group I No of pts***	***Group II No of pts***	***P value***
Cured	Primary	20	24	>0.05
	Recurrent	5	4	>0.05
Improved	Primary	2	1	>0.05
	Recurrent	0	0	No
Failed	Primary	3	1	>0.05
	Recurrent	0	0	No

The relation between the preoperative VLPP and the post-operative cured, improved or failed cases, the data revealed that cases with VLPP <60 Cm H_2O managed by TVT were failed but those who managed by fascial patch sling were succeeded with statistically significant difference between both groups (Table 15).

Table (15): The relation between preoperative VLPP and the post-operative cured, improved and failed cases.

Parameter	***VLPP***	***Group I No of pts***	***Group II No of pts***	***P value***
Cured	≥60 cm H_2O	25	24	>0.05
	<60	0	4	0.01
Improved	≥ 60	2	1	>0.05
	< 60	0	0	No
Failed	≥ 60	0	1	>0.05
	< 60	3	0	0.01

E- Post-operative follow-up:

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

The preoperative maximum flow rate (Q_{max}) was determined in each group in free flow and were found to be 28.7 ± 3.4 in group I and 29.8 ± 3.7 in group II with statistically insignificant difference in both groups preoperatively (P value >0.05).

Post-operatively there were highly statistically significant decreases in the post-operative Q_{max} in group II in comparison to group I at 6,12,18,24 months post-operatively (Table 16 and Fig. 52,53,54).

Table (16): The pre and post-operative Q_{max} in both groups.

Parameter	*Group (No)*	*Mean ± SD*	*T*	*P value*
Preop. Q_{max}	Group I	28.7 ± 3.4	1.5	>0.05
	Group II	29.8 ± 3.7		
Postop. Q_{max} 6ms	Group I (27/30)	22.9 ± 2.8	4.3	<0.001**
	Group II (26/30)	17.6 ± 2.3		
Postop. Q_{max} 12ms	Group I (30/30)	21.5 ± 3.2	4.1	<0.001**
	Group II (30/30)	16.8 ± 4.2		
Postop. Q_{max} 18ms	Group I (23/30)	21.7 ± 2.7	5.5	<0.001**
	Group II (25/30)	17.3 ± 2.5		
Postop. Q_{max} 24ms	Group I (22/30)	20.8 ± 3.4	2.6	<0.001**
	Group II (23/30)	16.7 ± 2.6		

** Highly significant.

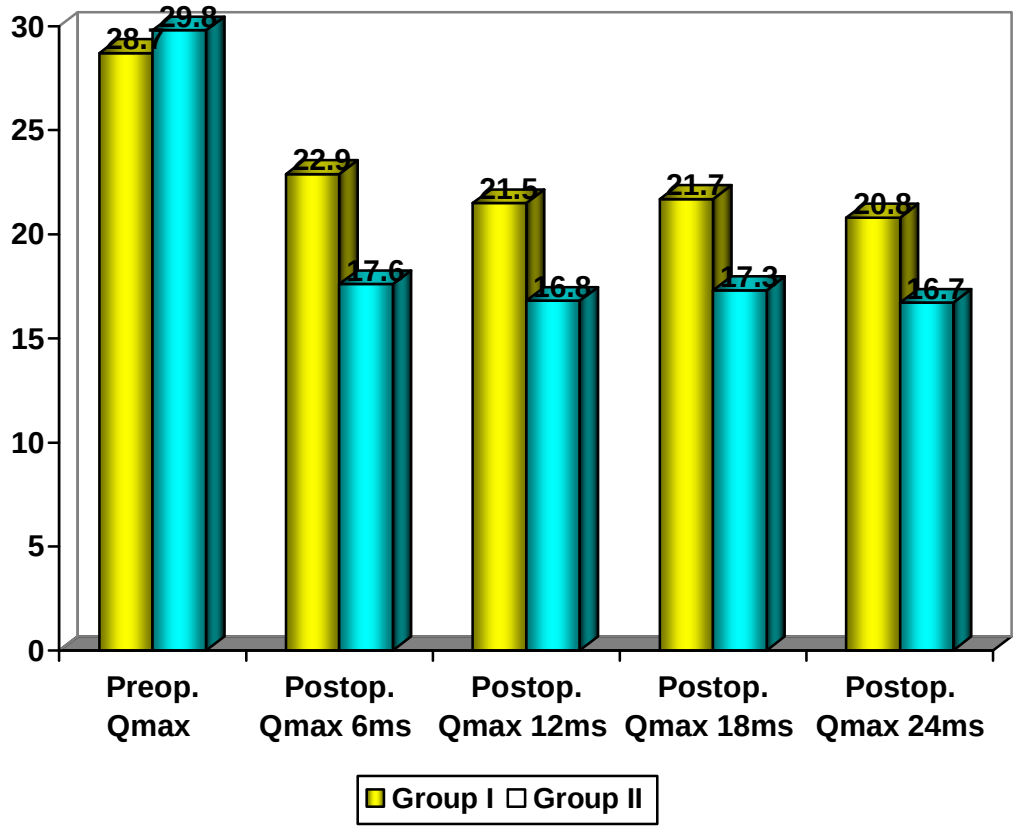
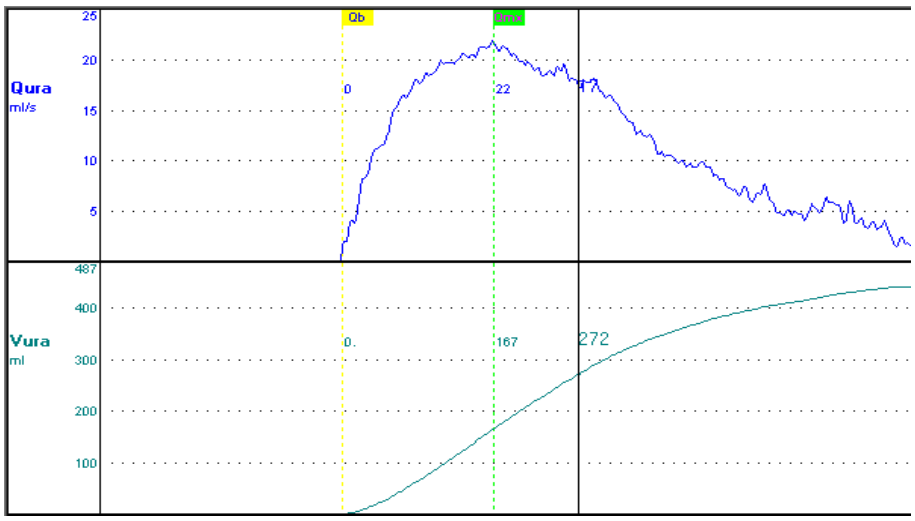


Fig. (52): The pre and post-operative Q_{max} in the studied groups.



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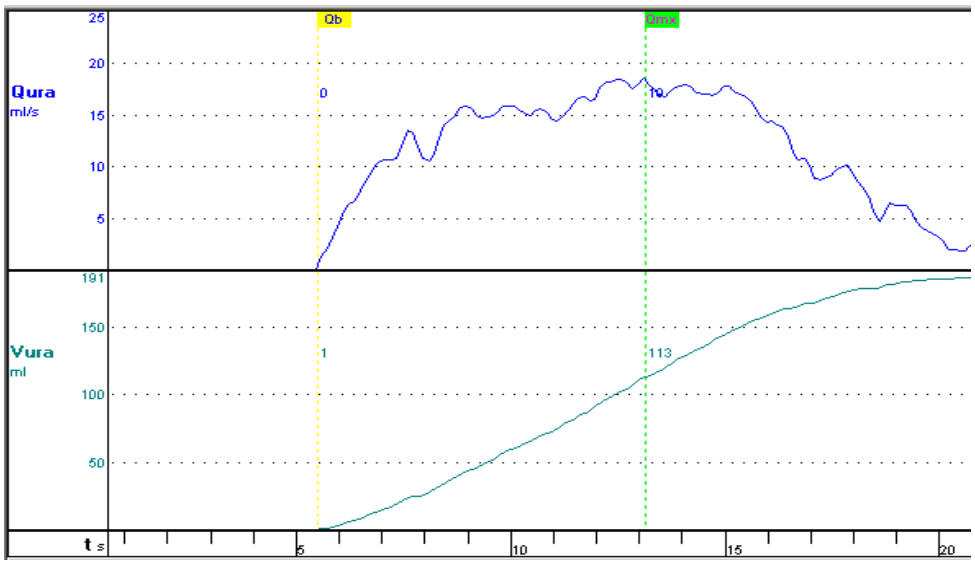
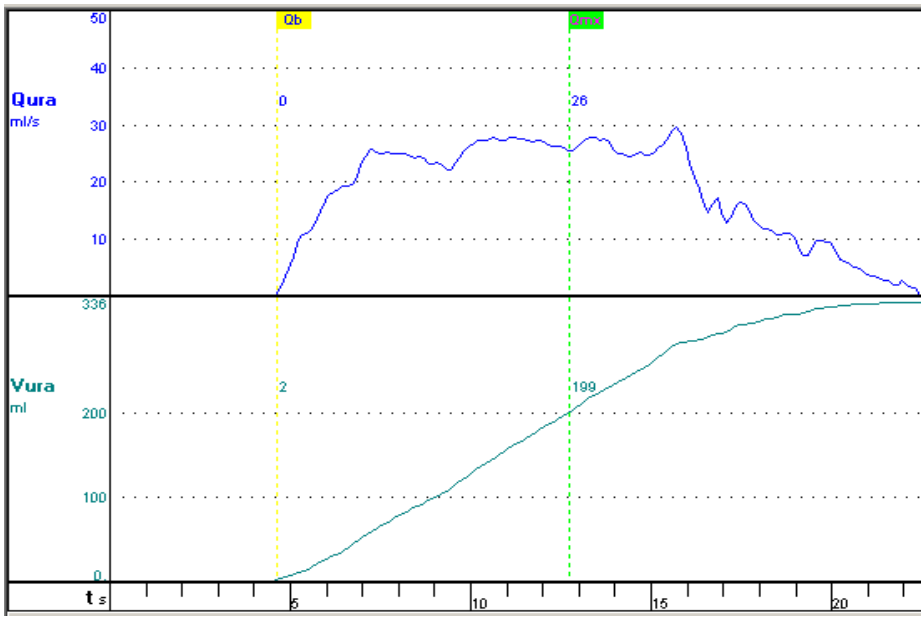


B

Fig. (53): Preoperative free flowmetry (A) and Post-operative free flowmetry: after one year (B) in group I (the same patient).



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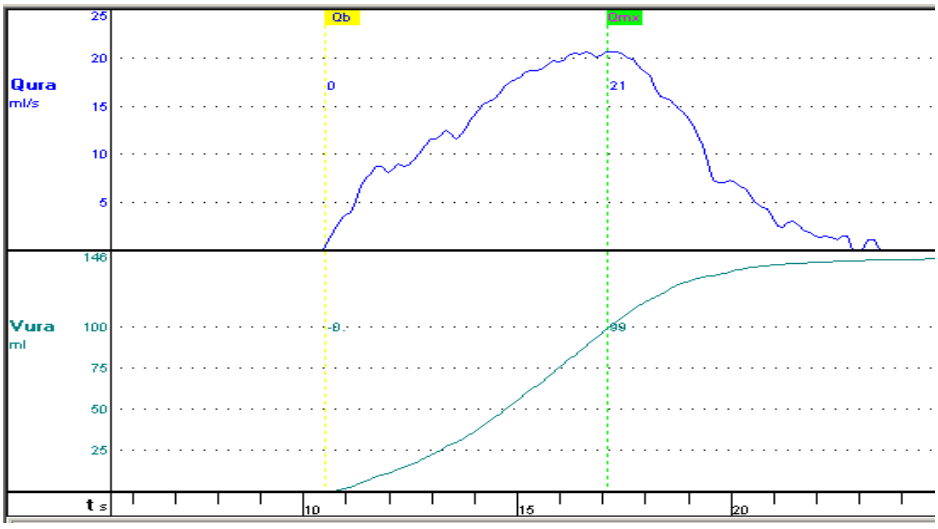

B

Fig. (54): Preoperative free flowmetry (A) and Post-operative free flowmetry: after one year (B) in group II (the same patient).

The preoperative post voiding residual urine (PVR) was statistically insignificant in both groups, but postoperatively there was highly statistically significant difference in both groups at 6,12,18 and 24 months post operatively with P value <0.001. Where in group I was less than that of group II (Table 17 and Fig. 55).

Table (17): The pre and post-operative difference in post-voiding residual urine in both groups.

Parameter	*Group (No)*	*Mean ± SD*	*t*	*P value*
Preop. PVR	Group I	16.2 ± 18.7	1.6	>0.05
	Group II	25.6 ± 26.4		
Postop. PVR 6 ms.	Group I (27/30)	32.5 ± 7.6	5	<0.001
	Group II (26/30)	56.2 ± 18.9		
Postop. PVR 12ms.	Group I (30/30)	30.7 ± 8.7	5.6	<0.001
	Group II (30/30)	57.8 ± 9.2		
Postop. PVR 18ms.	Group I (23/30)	32 ± 9.6	5.9	<0.001
	Group II (25/30)	59 ± 11.4		
Postop. PVR 24ms.	Group I (22/30)	30.5 ± 11.8	6.7	<0.001
	Group II (23/30)	59.4 ± 14.3		

** Highly significant.

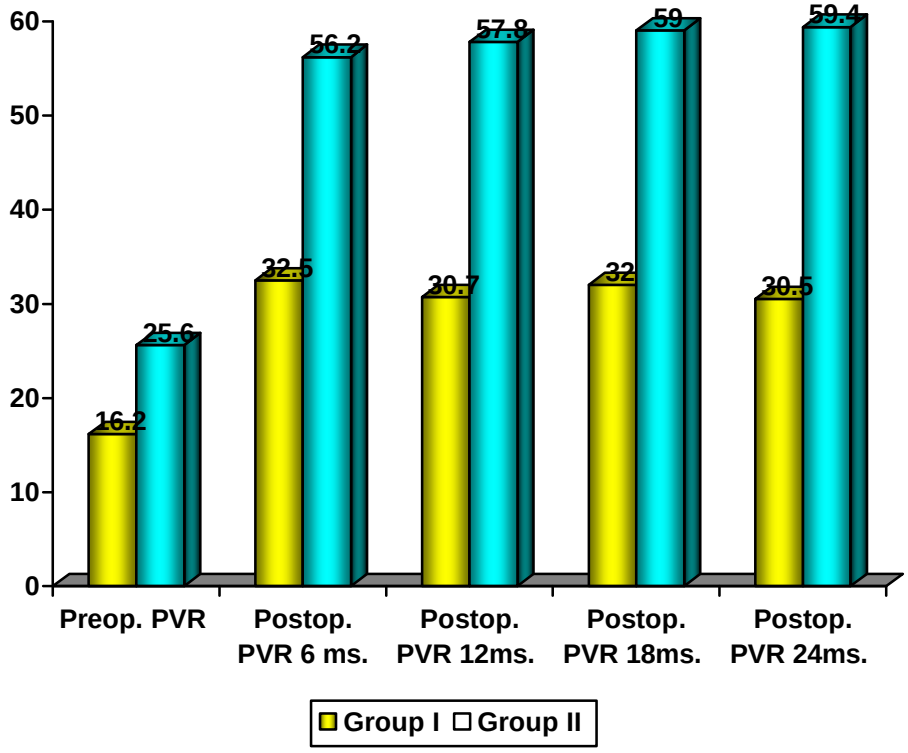

Fig. (55): Preoperative and post-operative residual urine in the studied groups

The maximum cystometric capacity revealed statistically insignificant difference in both groups preoperatively and post-operatively.

The detrusor pressure at maximum flow (P_{det} Q_{max}) was statistically significantly increased post-operatively in both groups with increase from 15.2 ± 9.7 to 20.4 ± 13.2 in group I and from 18.1 ± 8.7 to 23 ± 12.3 in group II with P value 0.01.

The pressure flow study was evaluated in both groups and we have found that after TVT procedure there was statistically significant decrease in Q_{max} from 18.7 ± 8.5 to 14.3 ± 64 with P value 0.01 and highly statistically significant decrease in Q_{max} from 20.3 ± 9.5 to 13.6 ± 5.8 in group II with P value 0.001 (Table 18,19 and Fig. 56,57,58,59,60,61).

Table (18): The maximum cystometric capacity Q_{max} and P_{det} Q_{max} pre and post-operatively in group I.

Parameters	***Preoperative***	***Post-operative***	***P***
	Mean ± S.D.	***Mean ± S.D.***	
Maximum cyst capacity	370 ± 130	360 ± 150	>0.05
Q_{max}	18.7 ± 8.5	14.3 ± 6.4	0.01*
P_{det} Q_{max}	15.2 ± 9.7	20.4 ± 13.2	0.01*

* Significant.

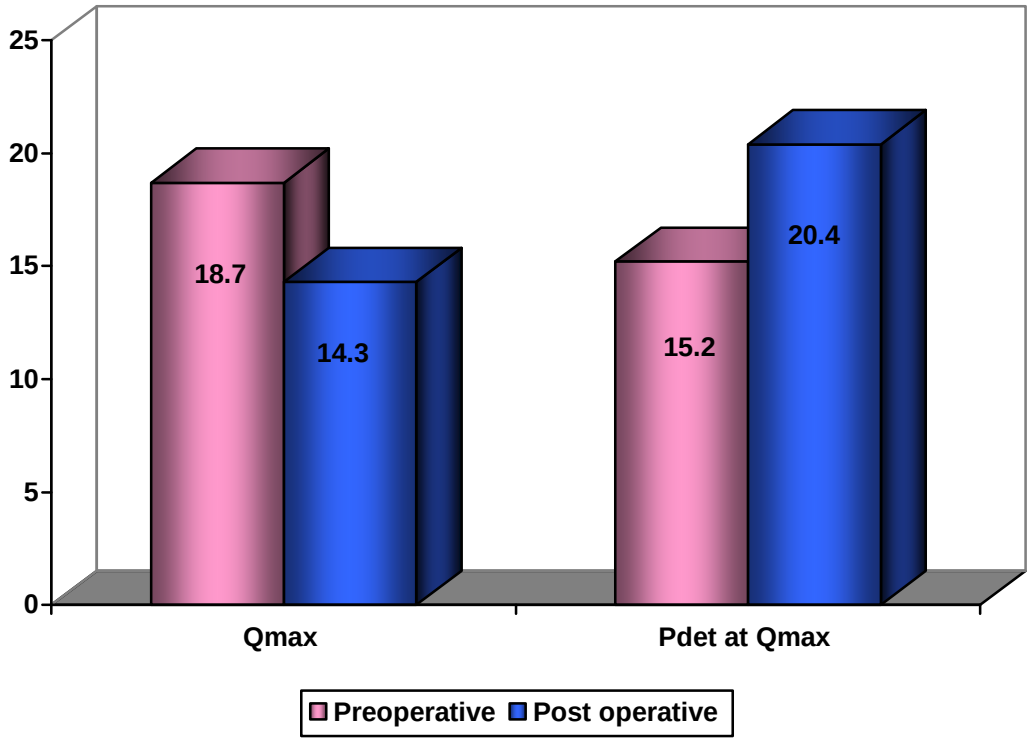

Fig. (56): The Q_{max} and P_{det} Q_{max} pre and post-operatively in group I.

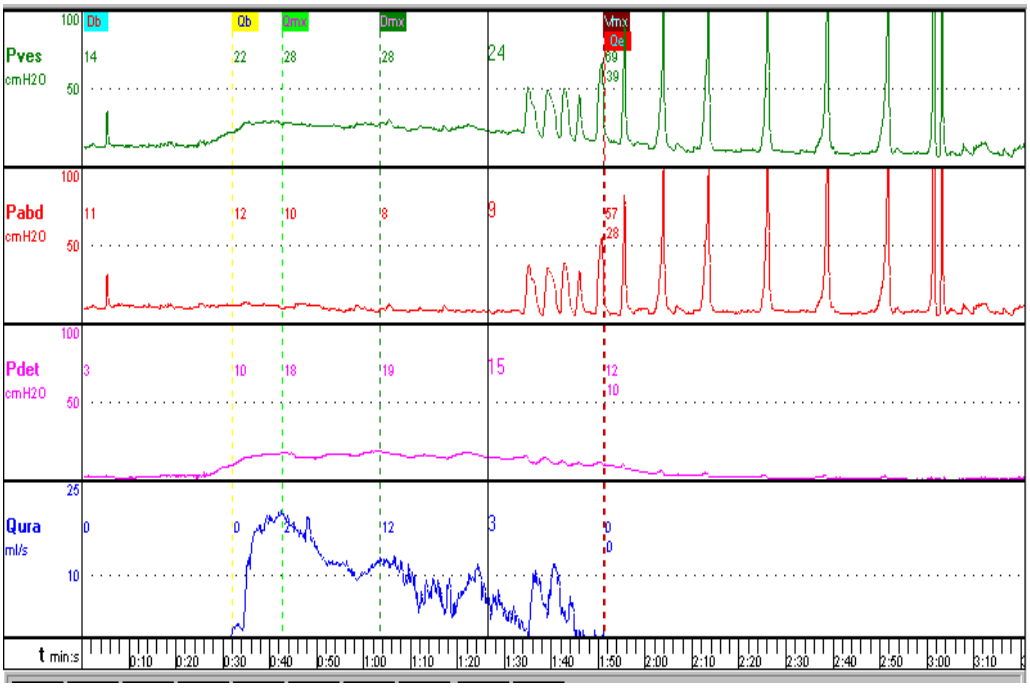

Fig. (57): Preoperative pressure flow study in group I.

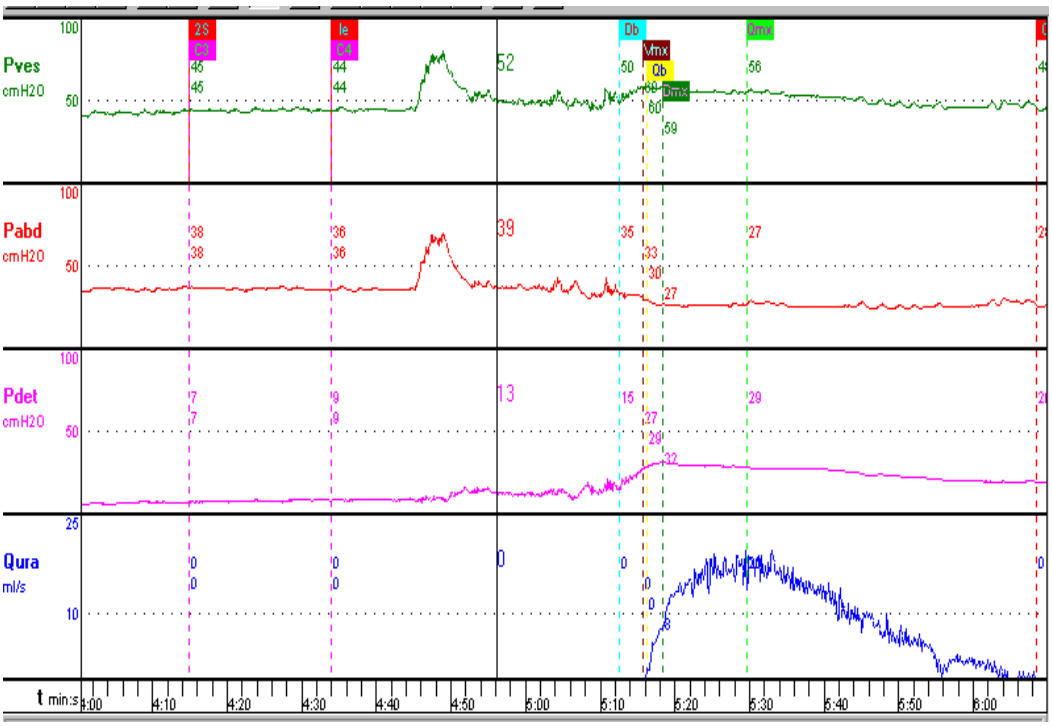

Fig. (58): Post-operative pressure flow study at one year in group II (the same patient).

Table (19): The maximum cystometric capacity, Q_{max} and P_{det} Q_{max} pre and post-operatively in group II.

Parameters	***Preoperative***	***Post-operative***	***P***
	Mean ± S.D.	***Mean ± S.D.***	
Q_{max}	20.3 ± 9.5	13.6 ± 5.8	>0.001**
Maximum cyst capacity	420 ± 120	405 ± 140	>0.05
P_{det} Q_{max}	18.1 ± 8.7	23 ± 12.3	0.01*

* Significant.
** Highly significant.

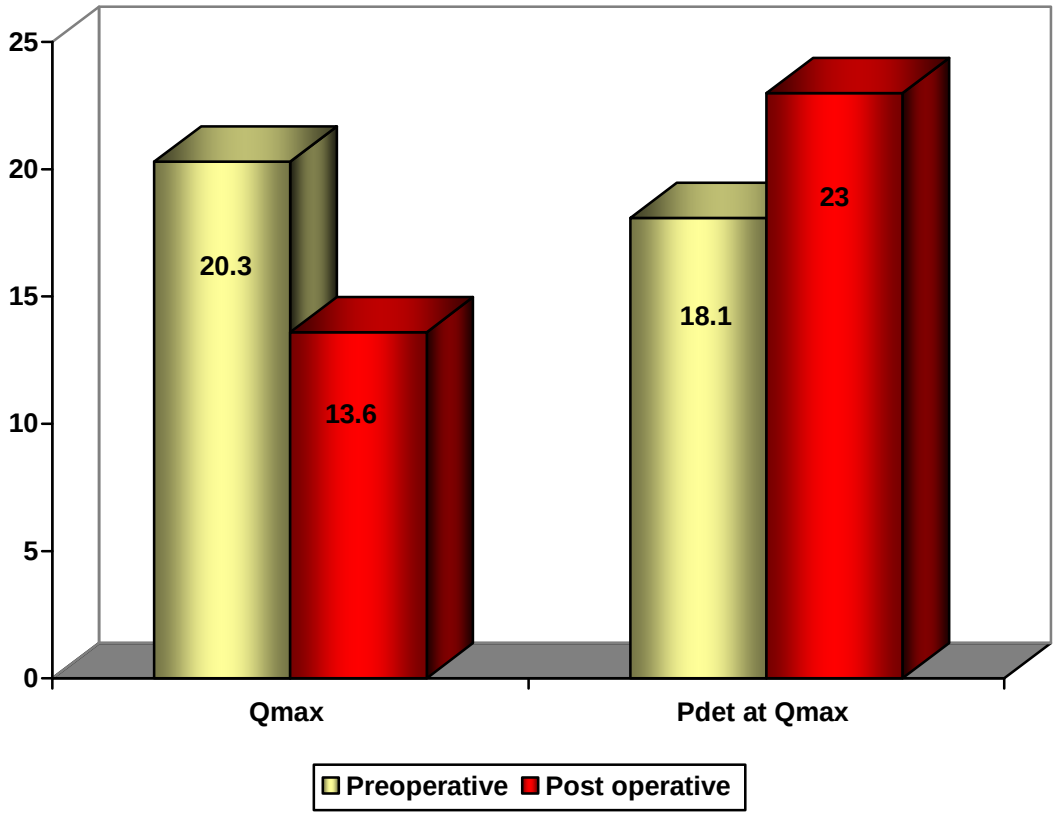

Fig. (59): The Q_{max} and P_{det} Q_{max} pre and post-operatively in group II.

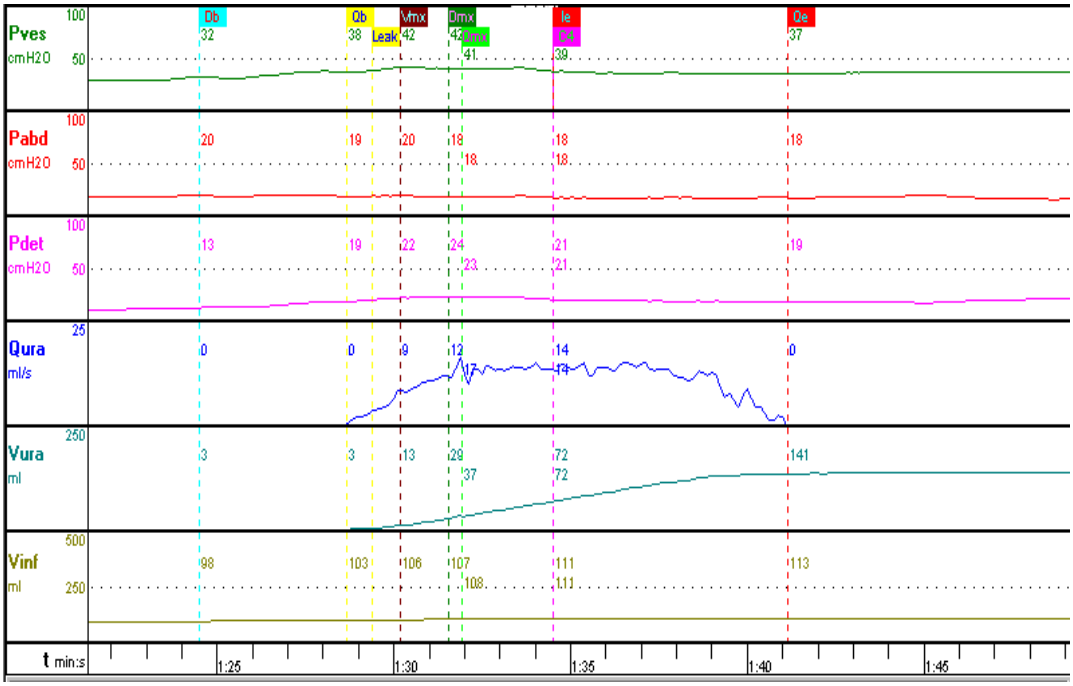

Fig. (60): Preoperative pressure flow study in group II.

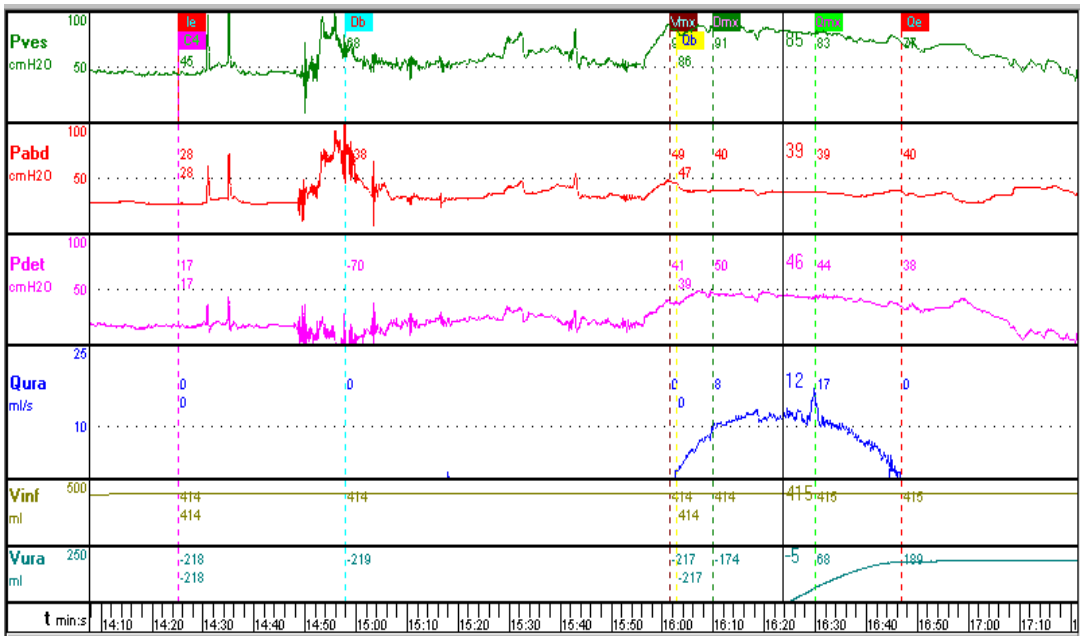

Fig. (61): Post-operative pressure flow study at one year in group II (the same patient).