RESULTS

Table (1)
Demography and base line Characteristics

a) Clinical data

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients	25	25	
- Recipients' age (year)*	29.88±11.36	29.36±10.22	0.868
- Recipients'sex (male:female)	20 : 5	16 : 9	0.207
- Recipients' body weight (kg)*	61.72±14.3	59.04±11.32	0.371
- Original kidney disease:			
* Mesangiocapillary GN	-	2	
* FSGS	1	--	
*Chronic tubulointerstitial dis.	3	2	
* Polycystic kidney	1	--	
* Renal Amyloidosis	--	2	
* End stage kidney (Biopsy)	16	15	
* Unknown	4	4	0.350
- Pretransplant hypertension	6	8	0.528
- History of Urinary bilharziasis	2	3	0.637
- Recipient HCV antibody: - (Positive: negative)	5 : 20	7 : 18	0.507

* values are expressed as mean ± standard deviation.

Table (1)

Demography and base line Characteristics

b) Donor/Recipient data

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients	25	25	
- Donors' age (year)*	36.76±9.13	34.2±11.22	0.196
- Consanguinity:			
*Related	22	20	
*Unrelated	3	5	0.478
- Donor/ Recipient blood group:			
*Same	23	22	
*different (compatible)	2	3	0637
- Tissue typing:			
Number of HLA (A&B) Matches:			
- Four mismatches	4	--	
- Three mismatches	1	7	
- Two mismatches	11	11	0.603
- One mismatch	4	4	
- Zero mismatch	5	3	
Number of DR Matches:			
- One mismatch	17	21	0.185
- Zero mismatch	8	4	

* values are expressed as mean ± standarddeviation.

Table (1)

Demography and base line Characteristics

c) Surgical aspects

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients	25	25	
- Ischemia time (minutes)*	46.52±13.35	52.64±11.50	0.053
- Time to duiresis:- (Immediate: delayed)	22 : 3	23 : 2	0.64
- Number of Renal arteries:- (One: more than one)	18 : 7	20 : 5	0.55

* values are expressed as mean ± standard deviation.

Table (1)

Demography and base line Characteristics

d) Laboratory prolife

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients	25	25	
	Mean±SD	Mean±SD	
• **Hematology:**			
Hemoglobin (gm/dl)	9.7±2.1	10.15±1.4	0.41
WBC (10^9/L)	11.2±7.2	11.7±4.3	0.12
Platelets (10^9/L)	288.7±67.8	277.1±52.4	0.86
• **Biochemistry:**			
Fasting blood sugar (mg/dL)	95.2±10.9	93.9±32.1	0.52
Serum calcium (mg/dL)	9.1±0.8	9.3±0.6	0.53
Serum phosphorus (mg/dL	5.7±1.9	6.4±2.1	0.43
Serum bilirubin (mg/dL)	0.5±0.2	0.6±0.3	0.91
SGOT (U/L)	29±8.2	27.9±10.5	0.43
SGPT (U/L)	27.6±12.4	26.6±8.8	0.28
Serum uric acid (mg/dL)	4.1±1.75	4.3±0.9	0.22
Serum cholesterol (mg/dL)	143.1±23.1	161.6±35.9	0.07
Triglycerides (mg/dL)	89.1±36.2	86.8±15.3	0.15
HDL (mg/dL)	37.1±6.3	38.2±5.1	0.81
LDL (mg/dL	99±32.8	98.7±35.4	0.72

Table (2)

a) Mean Tacrolimus (FK 506) level (ng/ml)

at different follow up periods in both Groups

	Group A (Steroid free)	Group B (Control)	P- value
	Mean±SD	Mean±SD	
1 week	12.3±3.1	12.1±4.2	0.83
2 week	11.6±2.7	11.9±3.5	0.81
1 month	11.49±4.64	11.74±4.78	0.83
3 months	7.64±3.32	9.16±3.10	0.09
6 months	7.05±2.50	7.50±2.17	0.57
12 months	6.24±2.00	6.88±1.85	0.36

There is a significant change over time, P = 0.031, by repeated measure ANOVA.

Table (2)

b) Mean Tacrolimus (FK 506) dosage (mg/day)

at different follow up periods in both Groups

	Group A (Steroid free)	Group B (Control)	P- value
	Mean±SD	Mean±SD	
1 week	8.51±3.2	11.5±3.1	0.04*
2 weeks	7.51±2.7	10.9±1.5	0.04*
1 month	6.84±3.62	10.36±4.71	0.01*
3 months	4.34±2.60	6.84±3.36	0.01*
6 months	4.00±2.50	5.96±2.95	0.02*
12 months	3.66±2.49	4.78±2.06	0.049*

There is a significant change over time, P = 0.008, by repeated measure ANOVA.

* P <0.05

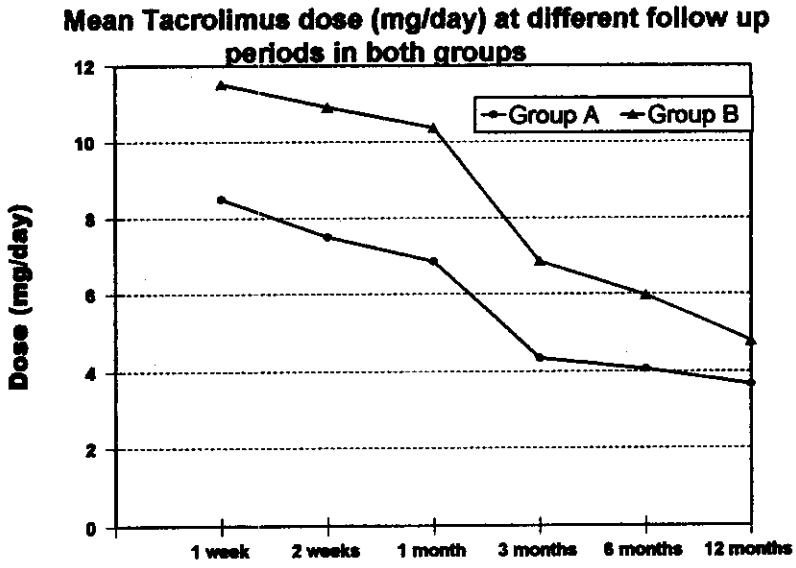

Mean Tacrolimus dose (mg/day) at different follow up periods in both groups
Dose (mg/day)
12
10
8
6
4
2
0
Group A
Group B
1 week
2 weeks
1 month
3 months
6 months
12 months

Diagram 1

Table (3)

Graft function in both groups at different follow up periods

a) Serum creatinine (mg/dL)

	Group A (Steroid free)	**Group B (Control)**	**P- value**
Follow-up period	n= 25	n=25	
1 week	1.6±1.3	1.2±1.4	0.12
2 weeks	1.8±1.7	1.2±0.5	0.04
1 month	1.6±0.8	1.1±0.3	0.01
3 months	1.3±0.4	1.3±0.3	0.56
6 months	1.3±0.4	1.2±0.3	0.51
12 months	1.3±0.5	1.3±0.34	1.00

b) Calculated GFR (ml/min)

	Group A (Steroid free)	**Group B (Control)**	**P- value**
Follow-up period	N= 25	N=25	
1 week	77.3±18.1	80.9±13.7	0.23
2 weeks	71.6±24.4	82.6±19.6	0.12
1 month	68.7±20.0	79.3±21.3	0.38
3 months	73.8±20.2	72.2±15.1	0.36
6 months	76.4±18.1	73.4±14.4	0.89
12 months	74.9±23.1	71.3±10.9	0.86

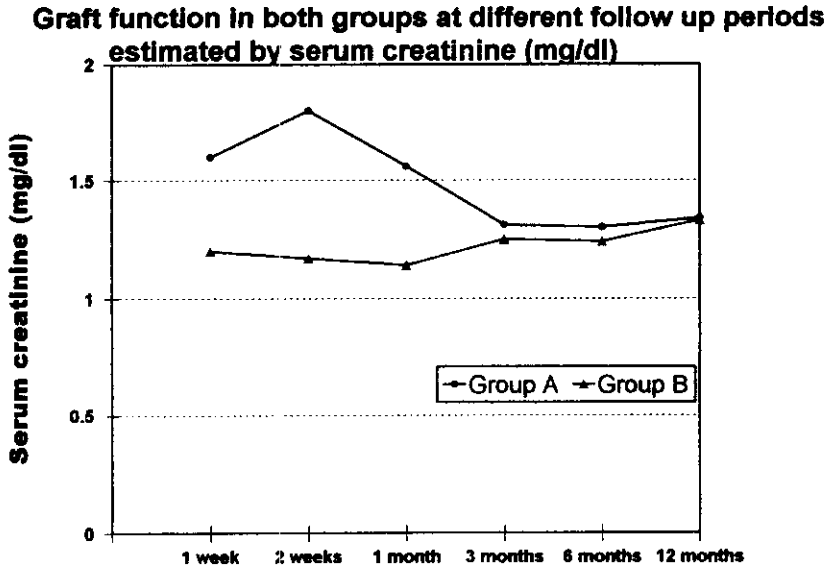

Graft function in both groups at different follow up periods estimated by serum creatinine (mg/dl)
Serum creatinine (mg/dl)
2
1.5
1
0.5
0
1 week
2 weeks
1 month
3 months
6 months
12 months
Group A
Group B

Diagram 2

Table (3)

Comparison of laboratory profile in both groups at different periods

c) Hematology

c-I) Hemoglobin (gm/dl)

	Group A (Steroid free)	Group B (Control)	P- value
	25	25	
Follow up period	**Mean±SD**	**Mean±SD**	
Basal	9.7±2.1	10.2±1.4	0.41
1 week	8.5±2.5	8.7±1.8	0.45
2 weeks	8.7±2.3	9.2±1.6	0.41
1 month	10.4±3.7	10.5±1.3	0.35
3 months	11.5±2.3	12.1±1.9	0.31
6 months	13.5±3.9	13.2±1.9	0.65
12 months	14.6±7.1	13.6±1.4	0.79

c-II White cell count (10^9/L)

	Group A (Steroid free)	Group B (Control)	P- value
	25	25	
Follow up period	**Mean±SD**	**Mean±SD**	
Basal	11.2±7.1	11.7±4.1	0.57
1 week	9.3±1.8	10.5±1.2	0.83
2 weeks	10.4±2.52	11.7±4.3	0.11
1 month	9.04±7.38	9.5±2.5	0.17
3 months	8.06±2.56	8.8±2.7	0.09
6 months	8.55±2.39	8.4±1.8	0.08
12 months	8.95±1.66	9.0±2.3	0.12

e-III) SGOT (U/L)

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients:	25	25	
	Mean±SD	**Mean±SD**	
Basal	29±8.2	27.9±10.5	0.42
1 week	26.3±7.3	28.7±11.3	0.45
2 weeks	25±8.24	27.96±10.51	0.425
1 month	29.88±11.02	31.04±12.15	0.051
3 months	26.68±10.11	34.48±11.47	0.009
6 months	29.56±10.06	33.44±9.97	0.246
12 months	26.56±7.65	31.48±10.26	0.134

Table (3)

Comparison of laboratory prolife in both groups at different periods

f) Lipid Prolife

f-I) Serum cholesterol (mg/dL)

	Group A (Steroid free)	**Group B (Control)**	**P- value**
Number of patients:	25	25	
Follow up period	**Mean±SD**	**Mean±SD**	
Basal	143.1±23	161.6±35.9	0.72
1 week	150±24.3	167.2±32.7	0.23
2 weeks	153.2±28.1	171.6±39.9	0.19
1 month	158.4±39.2	187.3±41.7	0.02
3 months	164.4±44.1	199.8±42.8	0.01
6 months	165.4±40.2	215.4±41.1	0.00
12 months	158.5±31.5	222.6±52.2	0.00

f-II) Serum Triglycerides (mg/dL)

	Group A (Steroid free)	**Group B (Control)**	**P- value**
Number of patients:	25	25	
Follow up period	**Mean±SD**	**Mean±SD**	
Basal	89±36.2	86.7±15.3	0.15
1 week	96±22.1	93.1±14.1	0.18
2 weeks	100.1±36.2	86.8±15.3	0.15
1 month	100.4±31.3	92.5±15.9	0.84
3 months	96.6±26.1	102.0±18.9	0.14
6 months	92.2±20.5	114.1±30.1	0.00
12 months	89.4±20.4	119.6±27.2	0.00

Table (3)
Comparison of laboratory prolife in both groups at different periods
d) Lipid Prolife
f-III) High density lipoproteins (mg/dL)

	Group A (Steroid free)	Group B (Control)	P- value
Follow up period	N= 25	N=25	
	Mean±SD	Mean±SD	
Basal	37.1 ±6.3	38.2±5.1	0.81
2 weeks	44.3±7.2	46.1±5.7	0.72
1 month	51.2±14.2	53.1±11.3	0.21
3 months	53.3±12.1	49.5±14.1	0.08
6 months	55.4±10.3	48.1±13.1	0.06
12 months	59.7±11.1	44.3±13.1	0.04*

f-IV) Low density lipoproteins (mg/dL)

	Group A (Steroid free)	Group B (Control)	P- value
Follow up period	N= 25	N= 25	
	Mean±SD	Mean±SD	
Basal	99±31.8	98.7±35	0.71
2 weeks	112±28.7	123.4±31.2	0.11
1 month	141.8±39.4	151.7±41.2	0.08
3 months	132.7±36.7	149.9±40.5	0.06
6 months	128.7±27.3	155.3±31.7	0.05*
12 months	129.8±29.7	157.2±21.7	0.04*

* $P<0.05$

Table (3)

Comparison of laboratory prolife in both groups at different periods g) 24 hour urinary protein excretion (gm/day)

Follow up period	Group A (Steroid free) N=25 Mean±SD	Group B (Control) N=25 Mean±SD	P- value
2 weeks	0.37±0.2	0.38±1.70	0.11
1 month	0.31±0.2	0.36±0.31	0.10
3 months	0.25±0.2	0.36±1.72	0.18
6 months	0.25±0.2	0.31±0.23	0.21
12 months	0.22±0.2	0.43±0.55	0.13

Table (4)

a) Acute rejection episodes

	Group A (Steroid free)	Group B (Control)
1- Incidence (Yes/No)	6/19 (24%)	6/19 (24%)
2- Frequency		
Non	19 (76%)	19 (76%)
Once	6 (24%)	6 (24%)
Twice	--	--
> twice	--	--
3- Severity		
Cellular	4 (16%)	4 (16%)
Humoral	2 (8%)	2 (8%)
4- Response to steroid treatment		
Steroid Responsive	4 (16%)	4 (16%)
Steroid Resistant	2 (8%)	2 (8%)
5- Timing		
Early	5 (20%)	2 (8%)
Late	1 (4%)	4 (16%)
6- No. of rejection/Patient (6 patients)	1/1	1/1

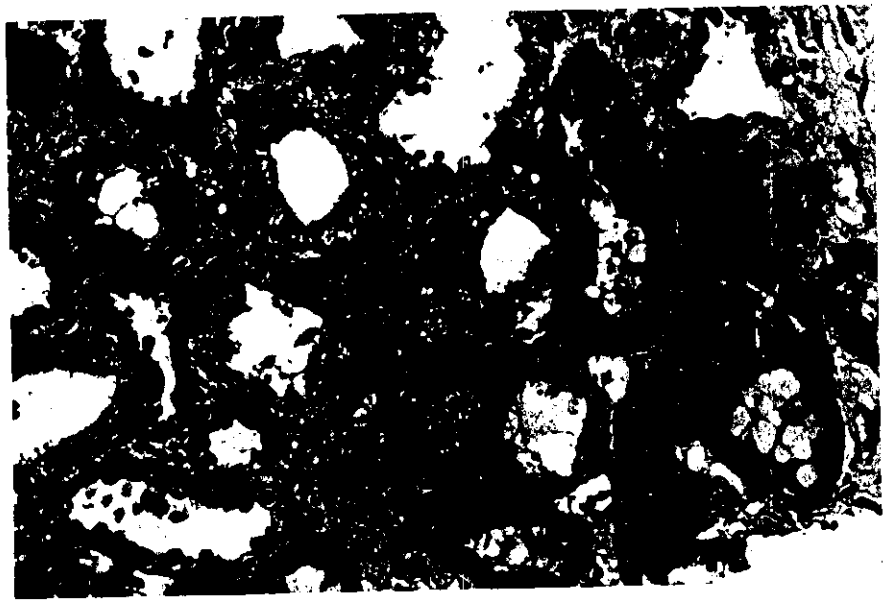


Fig (1) Acute FK toxicity, the tubules showed isometric Vaculization

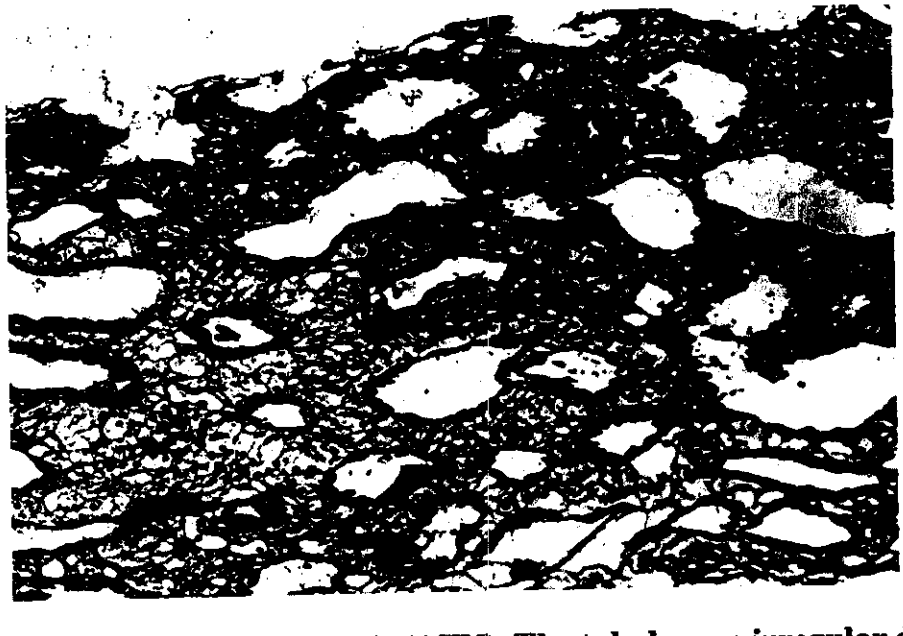


Fig (2) Acute tubular necrosis (ATN), The tubules are irregular dilated with attenuated epithelial lining. H&EX200

Fig (3) Border Line changes. The tubules show mild tabulates. H&EX400

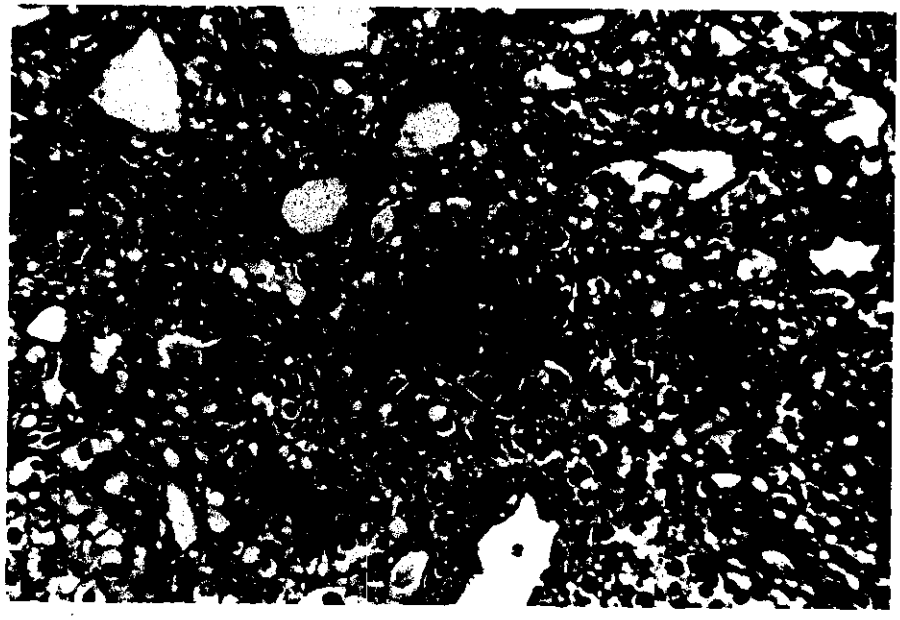


Fig (4). Acute rejection type Ia, according to Banff 97 the tubules show severe Tubulitis and interstitial inflammatory infiltrates. PASX400

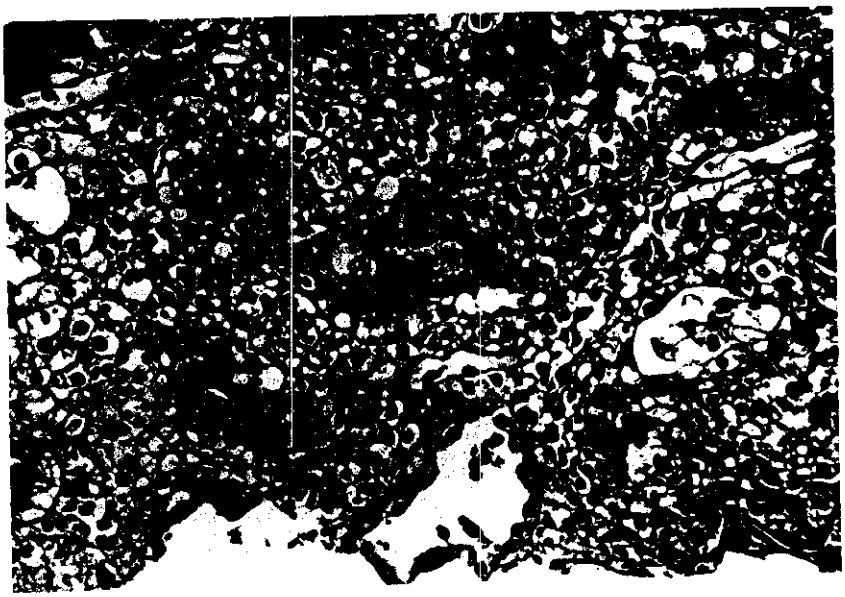


Fig (5) Acute rejection type Ib, according to Banff 97. The tubules how severe Tubulitis and interstitial inflammatory infiltrates. PASX400

Fig (6)Acute rejection Type IIa. According to Banff 97. The artery shows moderate subintimal arteritis H&EX200

Table (4)

b) Histopathologic examination of graft biopsies

(Event biopsy)

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients:	25	25	
Acute Rejection episodes:			
- Total number	6	6	
- Banff. Grade			
* Border line	4	3	
* Grade Ia	--	1	
* Grade IIa	2	2	0.479
Acute tubular necrosis	6	1	0.041
Acute FK nephrotoxicity	1	1	
Normal	5	1	
Number of biopsy/patient	18/25	9/25	

Table (4)
c-I) Chronic Allograft Damage Index
Of one year protocol biopsies
(CADI)

	Group A (Steroid free) (Mean ± SD)	Group B (Control) (Mean ± SD)	
-Mesangial Matrix Increase	0.20±0.41	0.24±0.44	
-Glomerular sclerosis	0.08±0.40	0.00±0.00	
-Tubular Atrophy	0.80±0.71	0.68±0.69	
-Interstitial inflammation	0.16±0.47	0.24±0.44	
-Interstitial fibrosis	0.84±0.75	0.84±0.80	
- Vascular intimal proliferation	0.4±0.20	0.28±0.54	
CADI score	2.48	2.28	P=0.169

c-II) Incidence of histological findings
in renal allograft protocol biopsies

	Group A (Steroid free)	Group B (Control)	P- value
-Mesangial Matrix Increase	20%	24%	0.74
-Glomerular sclerosis	4%	0%	0.32
-Tubular Atrophy	64%	56%	0.54
-Interstitial inflammation	12%	24%	0.32
-Interstitial fibrosis	64%	64%	0.97
Vascular intimal proliferation	4%	24%	0.42

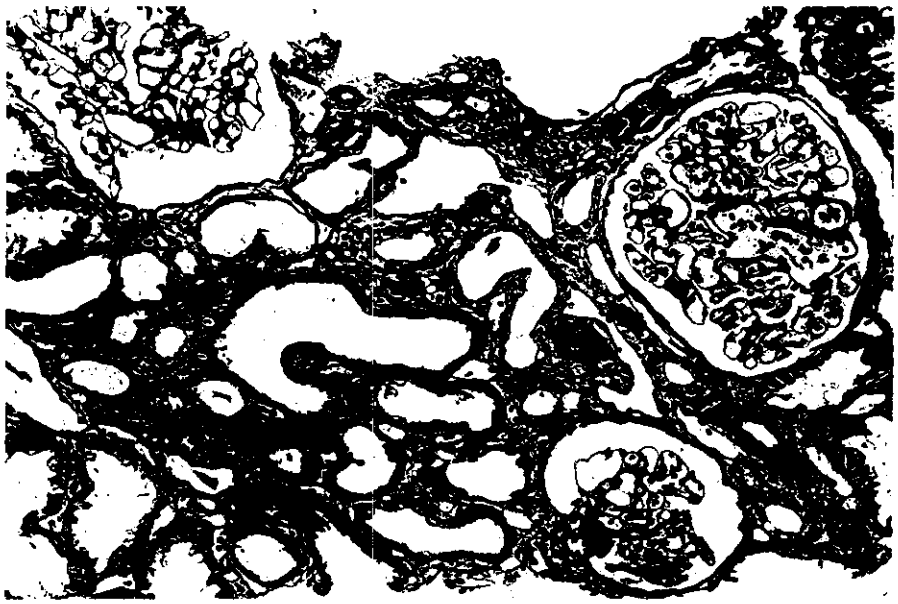
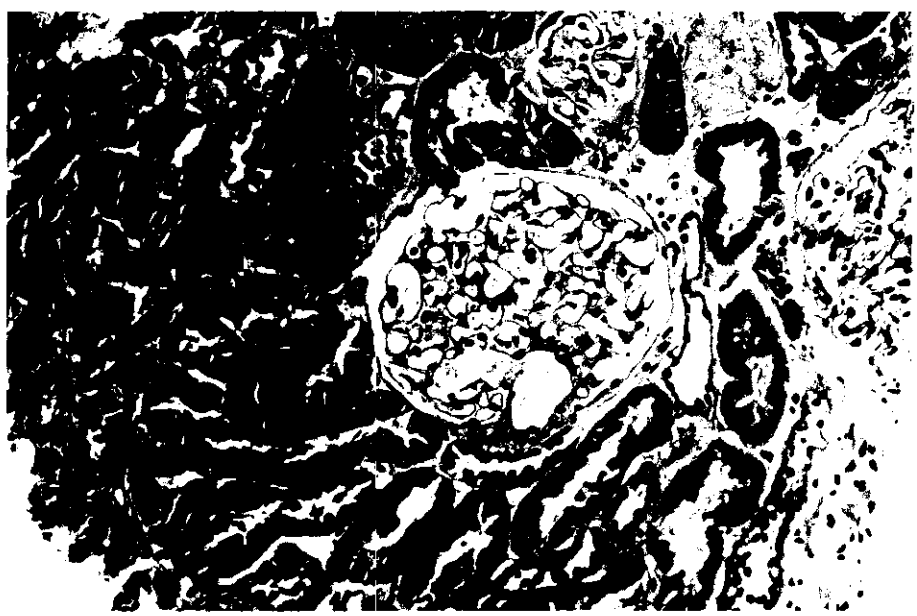


Fig (7) Protocol biopsy showed Mild focal tubulointerstitial fibrosis. Masson trichrome stainX200



Fig(8) Normal Graft H&E X200

d-) Time to 1st Rejection Episode

	Group A (Steroid free) (Mean ± SD)	Group B (Control) (Mean ± SD)	P- value
Range (days)	3-29	2-214	
Mean±SD	1.88±5.85	15±51.57	0.009
Time			
- 1 st week	5	3	
- 1st week >1 month	1	--	
- 1 month ≥ 3 months	--	1	
3 months >6th month	--	1	
6 months > 12th month	--	1	

Table (5)

Adverse events

a) Medical complications

a-I) Incidence of hypertension in both groups

	Group A	Group B
Pre study	24%	32%
At the end of the study	4%	44%

Degree of hypertension in both groups at the end of the study

	Group A	Group B
Mild	4%	12%
Moderate	0%	8%
Severe	0%	24%

Number of antihypertensive drugs used in both groups At the end of the study

	Group A (Steroid free)			No. of drugs /patient	(Control)			No. of drugs /patient	P-value
	One drug	2 drugs	3 drugs		One drug	2 drugs	3 drugs		
= Pre- study	24%	0%	0%	14/25	32%	0%	0%	8/25	0.528
= 1 month	4%	0%	0%	1/25	24%	8%	0%	10/25	0.0020
= 6 months	4%	0%	0%	1/25	12%	20%	0%	13/25	0.0020
= 12 months	4%	0%	0%	1/25	12%	8%	24%	25/25	0.0009

a-II) New onset Diabetes Mellitus

	Group A (Steroid free)	Group B (Control)	P- value
- Diabetes Mellitus (Yes/No)	1/24	4/21	
- Insulin dependant	--	4	0.037
- Non Insulin dependant	1	--	

a-III) Hyperlipidemia

	Group A (Steroid free)	Group B (Control)	P- value
-Hypercholesterolimic (Yes/No)	2/23	15/10	
- Hypertriglyceridemic (Yes/No)	5/20	12/13	0.029

Table (5)

a-IV) Hematologic complications

	Group A (Steroid free)	Group B (Control)	P- value
- Leukopenia	1	3	
- Thrombocytopenia	1	2	
- Anemi	2	2	
- Polycythemia	4	3	
- Leucocytosis	1	2	
- Thrombocytosis	1	1	0.341

a-V) Infections

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients:	25	25	
1- Type			
Bacterial			
- *UTI*	4	8	0.029
- Acute Bronchitis	2	5	0.036
- Pneumonia	1	4	0.165
- Abscess	2	4	0.395
Viral			
- CMV infection:	1	3	0.297
- *Herpes Zoster*	--	4	0.040
- *Herpes simplex*	1	3	0.29
Fungal			
- Fungal infection (systemic therapy)	2	4	0.395
2- Severity			
- Admission (Yes/No)	5/25	12/25	0.03

Table (5)

a-VI) Proteinuria

	Group A (Steroid free)	Group B (Control)	P- value
*0.5-1 gm	1	5	
* 1-2 gm	1	1	
Total number	2	6	0.000

aVII) Hepatitis

	Group A (Steroid free)	Group B (Control)	P- value
Affected patients (Yes/No)	4/21	7/18	0.370
1- Cause			
Viral	3	5	
Toxic	1	2	
2- Severity			
Acute	3	4	
Chronic	1	3	
3- Type			
Isolated hyperbilirbinemia	1	1	
High Transaminases	3	6	

Table (5)

a-VIII) Temporal of body weight

	Group A	Group B
Basal Body weight	61.72±14.30	59.04±11.32
2 weeks	63.20±15.12	60.28±11.44
1 month	63.66±14.86	60.84±12.44
3 months	64.88±15.34	64.76±12.39
6 months	66.24±15.9	68.44±13.77
12 months	67.80±16.20	70.52± 14.51

There is a significant change overtime, P<0.0001, by repeated measure ANOVA.

: Weight gain changes throughout the follow up periods in both groups

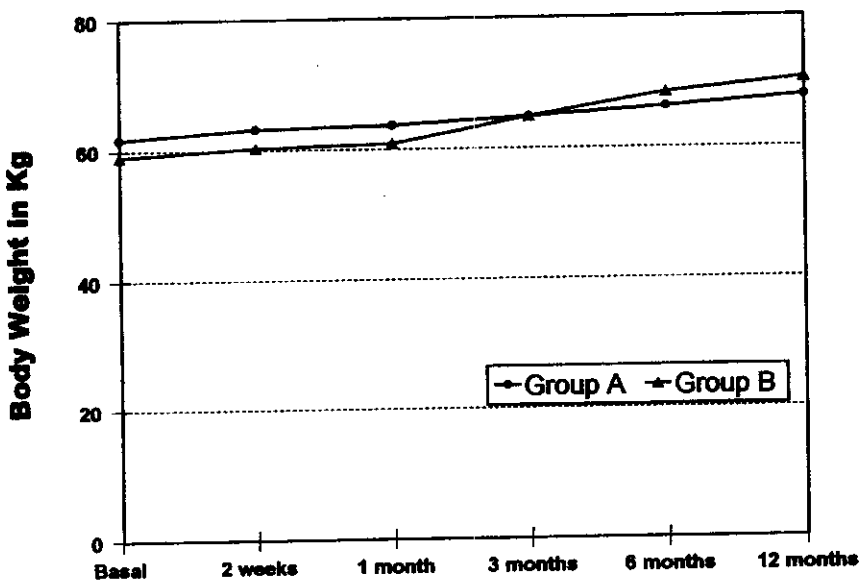


Diagram 3

Table (5)

a IX) Other medical complications

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients:	**25**	**25**	
- *Gastritis*	9	6	0.390
- Bone ache & Arthralgia	2	8	0.042
- Acne	-	10	0.001
- DVT	-	1	

Adverse events

a.X) Surgical complications

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients:	**25**	**25**	
- Lymphocele	-	3	
- Wound infection	-	1	
- Wound sinus	-	1	
- Wound gapping	-	2	

Table (6)

Patient & Graft outcome at the end of the study (12 months)

	Group A (Steroid free)	Group B (Control)	P- value
Number of patients:	**25**	**25**	
- Graft survival:	100%	100%	
- Follow up period (months:			
• Mean ± SD	12.73±2.46	13.73±2.56	
Patient outcome:			
- Mortality	--	--	
- Living:			
* with functioning graft	25	25	
*Return to hemodialysis	--	--	
- Out of study:			
*MMF withdrawal	1	2	0.500
* Cross over	4	-	0.037

Clinical Gading of Functioning Grafts in both groups

(one year post transplant)

	Group A (Steroid free)	Group B (Control)
1- Excellent: Cr <1.5 mg/dl	19	22
2- Moderate: 1.5< Cr <3mg/dl	6	3
3- Impaired: Cr >3.5 mg/dl	--	--

Demography and baseline characteristics

• **Clinical data:**

Both groups were homogenous regarding demographic and base line characteristics including age, sex, body weight as well as original kidney disease. Higher prevalence of pretransplant hypertension was noticed in control group (group B) (32%) in comparison to steroid free group (group A), as well as pretransplant positive anti hepatitis C virus (HCV) antibodies was noticed to be ; 25% and 32% in group A and B respectively. Additionally, urinary bilharziasis diagnosed by urinary panendoscopy was found in 8% of cases among group A and 12% of group B patients (Table 1.a).

• **Donor/recipient data:**

Mean donors' age was 36.7 and 34.2 years in group A and B respectively (p=0.196). The majority of donors were related being parents, sibilings or off springs while unrelated donors constitute 12% and 20% of group A and B respectively (p=0.478). Regarding donor /recipient blood groups, different but compatible blood groups constitute 8% and 12% among group A and B respectively (P=0.637). The commonest pattern of HLA tissue typing was two mismatches constituting 44% in both groups, meanwhile one DR mismatch was the commonest patter of DR tissue typing constituting 68% and 84% in group A and B respectively (Table 1.b).

• **Surgical aspects:**

Mean ischemia time was comparable in both groups (P=0.053) as well as time to onset of diuresis except for three cases among group A and two cases in group B whom diuresis was delayed. The majority of renal allografts in both groups have single renal artery (Table 1.c)

• **Laboratory data:**

Hematologic criteria regarding hemoglobin, leucocytic count, as well as platelet count were comparable in both groups without statistical significant difference. In another hand, liver function tests, fasting lipid profile, fasting blood sugar as well as serum calcium, phosphorous and uric acid values were comparable in both groups (Table 1.d).

Immunosuppressive medications:

• **Mean tacrolimus dosage at different follow up periods in both groups:**

Mean tacrolimus dose required to achieve target trough level showed significant reduction in group A in comparison to group B over time and it was noticed that (p=0.008) in first month, (p=0.010) in third month, (p=0.024) in sixth month and (p=0.049) at one year. Mean tacrolimus dose reached the maximum value 8.51 mg/day (0.14 mg/kg/day) in group A in comparison to group B; 11.5 mg/day (0.19 mg/kg/day) by the end of first week post-transplantation, while mean tacrolimus dose reached the minimum value 3.66 mg/day (0.05 mg/day) in group A in comparison to group B; 4.78 mg/day(0.068 mg/kg/day) by the end of one year post-

transplantation. Significant reduction of mean tacrolimus dose over time was noticed (p=0.008). The mean starting dose of tacrolimus was 6.17 mg/day and 5.9 mg/day (calculated from mean body weight x 0.1 mg/kg/day). On the other hand, mean tacrolimus trough level was kept within the target window (5-8 ng/ml) throughout whole study follow up periods (Table 2.a)

- **Graft function in both groups at different follow up periods:**

A trend towards better graft function as measured by serum creatinine and calculated GFR was noticed among patients of group B at different time points till the sixth month where group A was noticed to have a better graft function ; however it did not rank to statistical significance (table 3.a & 3.b) and (Figure 2).

- **Comparison of laboratory profile in both groups at different periods:**

Hematology:

Mean hemoglobin values and white cell count were comparable in both groups at different time points. Regarding mean platelet count, significant lower values were noticed among group A patients at 6 and 12 months post-transplantation (Table 3.C.I & 3.C.II & 3.C.III).

Biochemistry:

Mean serum calcium levels were comparable in both groups as well as mean serum phosphorus levels (Table3. d.I & 3.d.II). Mean serum uric acid values were also comparable in both groups at different time (Table 3.d.III).

Liver function tests

Normal and comparable mean serum bilirubin values were noticed among both groups except at three and twelve months where group A had statistically significant lower mean value (Table 3.e.I). On the other hand, mean SGPT had statistically significant lower mean value at one and six months in group A ,while SGOT values were comparable except at three months where group A had lower mean values (Table 3.e.II & 3.e.III).

*** Lipid Profile***

Mean serum cholesterol levels were comparable in both groups until two weeks; however group B patients had significant higher elevations than group A throughout the whole study period (Table 3.f.I). Similarly, serum triglyceride, were comparable in both groups at two weeks, one month and three months, but group A patients had significantly lower mean values at six months and one year. HDL and LDL mean values were elevated in both groups, being higher in group B than group A, however they did not rank to statistical significance except at one year (HDL) and sixth month and one year (LDL) (Table 3.F.II & 3.F.III & 3.F.IV).

***Twenty four hour urinary protein excretion:**

Quantitative proteinuria showed higher excretory rates in group B patients however, being insignificant throughout the whole study period (Table 3.g).

• **Incidence and frequency of acute rejection episodes:**

The impact of steroid free immunosuppression was not reflected on the incidence and frequency of acute rejection episodes being comparable in both groups patients (24%) (Table 4.a & 4.b).

• **Histopathologic examination of graft biopsies:**

Renal allograft tissue histopathologic examination was carried out in cases of delayed graft function, and episodes of graft dysfunction. In addition to acute rejection discussed above, Other pathologic diagnoses included acute tacrolimus nephrotoxicity and acute tubular necrosis in one and six cases respectively among group A patients and one case in both diagnoses among group B patients (Table 4.B).

• **Chronic allograft damage index of one year protocol biopsies (CADI):**

Higher CADI score in group A than group B patients was noticed however it did not reach statistical significance (P=0.169) (Table 4.C.I). Regarding incidence of histopathologic findings in renal allograft protocol biopsies, Tubular atrophy and Glomerular sclerosis were higher among group A than group B patients however it did not reach statistical significance (P=0.54) and (P=0.32) respectively. Mesangial matrix increase , Interstitial inflammation and Vascular intimal proliferation were higher in group B than group A patients however it did not reach statistical significance (P=0.74) ,(P=0.32) and (P=0.42) respectively. However, interstitial fibrosis were equal in both groups patients (Table 4.C.II).

- **Adverse Events:**

*** Change in the control of hypertension in both groups:**

Number of patients suffering from hypertension had decreased from 24% pre transplant to 4% post transplant in group A and had increased from 32% pre transplant to 44% post transplant in group B with high significance at one ,six and twelve months (P =0.002), (P =0.002) and (P =0.0009) respectively (Table 5.a.I).

*** New onset diabetes mellitus:**

Significant higher incidence of new onset diabetes mellitus was observed among group B patients (16%) in comparison to group A (4%) (P =0.037) (Table 5.a.II).

*** Hyperlipidemia:**

The number of patients suffered from hypercholesterolemia were higher in group B than group A being 8 % in group A and 60 % in group B with statistical significant difference between the two groups (P =0.029) (table 5.a.III).

*** Hematologic abnormalities:**

The incidence of leukopenia was insignificantly higher in group B than group A being 12% versus 4% respectively (p =0.187). On the other hand two cases of thrombocytopenia were diagnosed among group B patients (8%) and one patient in group A (4%), other abnormalities are comparable and insignificant (P = 0.34) (table 5.a.IV).

*** Infections:**

Significant differences were encountered regarding the incidence of most types of infections between the two groups being higher in group B than group A, e.g. urinary tract infections, acute bronchitis, and herpes zoster (P =0.029, 0.036 and 0.040 respectively) On the other hand, pneumonia, skin abscesses, CMV infection and fungal infections were higher in group B patients without significant difference.

(P =0.165, 0.395, 0.297 and 0.395 respectively) (Table 5.a.V).

*** Proteinuria:**

Higher incidence of proteinuria was reported among group B patients being 24% in comparison to 8% in group A which reached statistical significance (P =0.000) (Table 5.a.VI).

*** Hepatitis:**

Among group A and B patients, 16% and 28% of patients were encountered to have high SGPT and SGOT serum values at least at one occasion (Table 5.a.VII).

*** Bone disease:**

Avascular bone necrosis was encountered in one patient in group B after one year follow up.

*** Weight gain:**

There was a significant increase of body weight in group B patients in comparison to group A patients over the time of follow up periods (P<0.0001) (Table 5.a. VIII).

*** Other medical complications**

Insignificant higher incidence of recurrent attacks of diarrhea (requiring hospital admission) was noticed among group A patients (P=0.390). High incidence of bone ache and arthralgia was noticed in group B patients which was significant (P=0.042). In addition, cases of acne were significantly more frequent in group B (P=0.001). Deep vein thrombosis (DVT) was encountered in one patient in group B.

*** Surgical complications:**

The incidence of lymphoceles was higher in group B (12%) while group A had no cases with lymphoceles (P=0.030). Additionally, one case of wound infection, wound sinus and two cases of wound gapping were encountered in group B (table 5.a.X).

• **Patient and graft outcome:**

The overall graft and patient survival were 100% in both groups at one year posttransplant. Additionally, crossover from group A to group B was carried out in 4 cases (P=0.037) (Table 6) .MMF withdrawal due to gastric upset was carried out in one case in group A and two cases in group B .