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A PROSPECTIVE OBSERVATIONAL STUDY ON CLINICAL SAFETY AND EFFICACY OF IMMUNOSUPPRESANTS USED INTHE LIVER TRANSPLANT RECIPIENTS

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ABSTRACT

Background: Nearly eight thousand liver transplantation occurs every year. Within the first year following their transplant, recipients of deceased donor livers had a seven percent prevalence of allograft failure. **Methodology:** Our Research project was an observational study which includes 68 individuals to assess outcomes and safety of research of immunosuppressants used in liver transplantation. **Results:** According to our research effort, immunosuppressants were mostly administered and shown their efficacy in liver transplant patients by lowering rejection rates. Immunosuppressants were administered in triple regimens for 25.7% of the population and in dual medication regimens for 74.28% of patients. **Conclusion:** 70% of patients obtained an order for tacrolimus, 20% for cyclosporine, and 10% for mycophenolate mofetil, among other immunosuppressants. Mostly these drugs are given in the combination of TAC + CYC.

KEYWORDS: A Prospective Observational Study, Clinical Safety, Immunosuppressants, Liver Transplant Recipients.

INTRODUCTION

Improvements in surgical technique and perioperative care have gradually enhanced outcomes of solid organ transplantation. Immunosuppressive handling is crucial for allograft and patient survival. During the early years of transplantation, steroids and azathioprine were the only available agents to manage the host immune response against the graft; currently, several compounds can guide the donor–recipient interaction.[1,2]

Numerous studies have been conducted to identify the most effective and less toxic immunosuppression regimen to protect both the graft and recipient,[3,4,5] Unfortunately, few studies have adhered to the five criteria defined by Jadad: randomization, blinding, adequate description of the randomization and blinding procedures, and intention to treat follow-up with mention of all dropouts or withdrawals from the study. This partly explains the ongoing search for an ideal treatment regimen.[6] A detailed literature review covering the period 2001–2021 identified only seven double-blinded, prospective, and randomized controlled trials (RCTs) with 50 or more participants; four failed to afford any relevant conclusions for clinical practice,[7,8,9,10,11,12,13,14] Despite the initial observations by Starzl.[1] regarding graft acceptance from both large animals and humans, multi-agent immunosuppression resulted in the best means to prevent "repudiation of the allograft." This policy often generates over-immunosuppression, which is responsible for the development of potentially fatal metabolic (40%), cardiovascular (20%), renal (20%), and oncological and infectious complications (10%–20%) in a high proportion of recipients,[15,16] These side effects explain why long-term outcomes post-transplantation have not significantly improved during the last 20 years and why recipient death with a functioning graft is the most common cause of late graft loss.[3,4]

Need for the study is Liver transplant is an extensive surgical procedure with many risks. Immunosuppressive drugs are prescribed to recipients of

liver transplants to prevent rejections. Therefore, it is important to research the various medication types administered to recipients to determine the effectiveness of these drugs and to determine the safety and efficacy of our hospital's recommended immunosuppressive medication regimen.

The primary aim of the project is to evaluate the prescribing patterns in Liver transplant recipients. The objectives are to evaluate the use of - Immunosuppressants. To evaluate the prescribing pattern in the patients with comorbidities. To examine our hospital's preferred immunosuppressive medication regimen.

MATERIALS AND METHODS

STUDY DESIGN: A prospective observational study.

INCLUSION CRITERIA

- Every patient who received a liver replacement.
- Hepatology department.
- Individuals prepared to give informed permission.

EXCLUSION CRITERIA

- Pregnant
- Psychiatric patients.
- Cancer patients.

STUDY PERIODS: 6 Months.
SAMPLE SIZE: 68 Samples

SOURCE OF DATA COLLECTION

- Data gathering form for the patient.
- From IP and OP departments.

RESULTS

GENDER WISE DISTRIBUTION

49 (70.05%) of the 68 patients were found to be male, and 19 (27.94%) to be female.

Table 1: Gender wise distribution.

GENDER	TOTAL NUMBER OF PATIENTS	PERCENTAGE
MALE	49	72.05%
FEMALE	19	27.94%

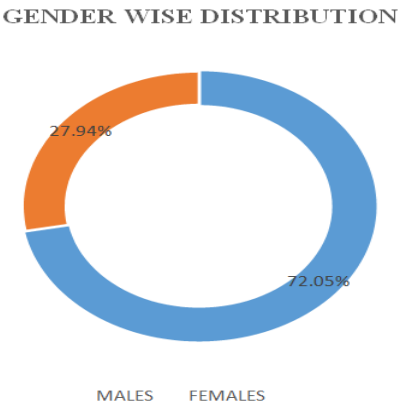


FIGURE: 1: - GENDER WISE DISTRIBUTION.

PATIENTS DISPERSED BY AGE

Total age was categorized at the interval of 7. of the 68 patients, 14 fell within the 0–10 age range, 03 were between the 11–20 age range, seven patients ranged in age from twenty-one to thirty. Nine patients belonged to the ae groupunder thirty-nine, sixteen were in the center of forty-one to fifty, sixteen were in the middle offifty to sixty, and three were in the range of sixty to seventy.

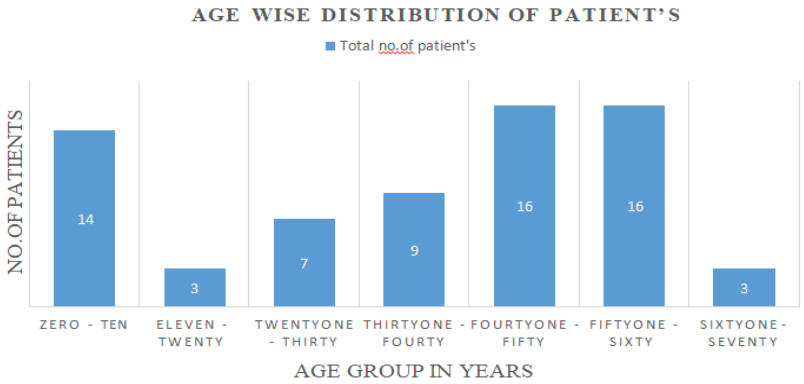


Figure 2: PATIENTS DISPERSED BY AGE.

PATIENTS BY AGE AND GENDER DISTRIBUTION

Six of the 19 female patients were in the middle of the 0–10 age group, two were between the 11–20 age category, three were 21–30 age, two were between the 31–40 age range, four were between the 41–50 age range, and two were in the middle of the 51–60 age range. of the 49 male patients, eight were in the 0–10 age range, one was in the 11–20 age group, four were 21–30 age category, seven were 31–40 age range, twelve were 41–50 age range, thirteen fell 51–60 age range, and three were 61–70 age range.

Table 3: PATIENTS BY AGE AND GENDER DISTRIBUTION.

AGE	MALE	FEMALE
0-10	8	6
11-20	1	2
21-30	4	3
31-40	7	2
41-50	12	4
51-60	14	2
61-70	03	0

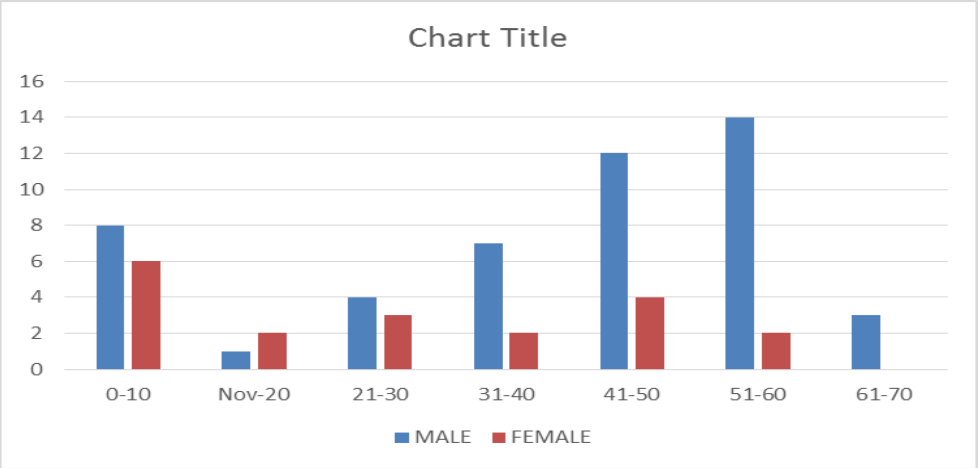


Figure: 3 - PATIENTS BY AGE AND GENDER DISTRIBUTION.

PATIENTS ARE ARRANGED BASED ON OTHER MEDICAL CONDITIONS

Of the sixty-eight patients, forty-four had co-morbidities and twenty-four did not.

Table 4: Patients are arranged based on other medical conditions.

People with co-morbidities	people with no co-morbidities
44	24

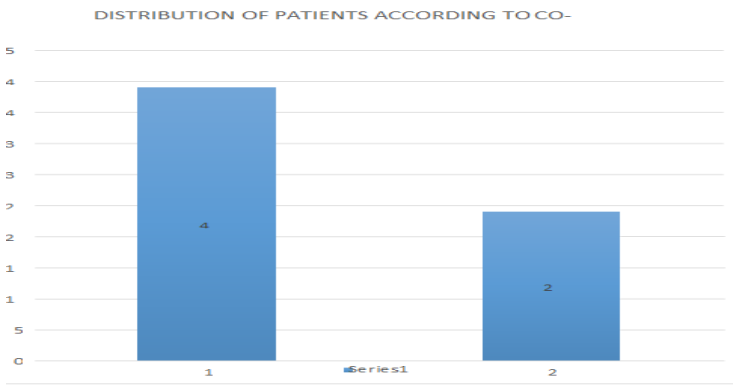


Figure 4: - Patients are arranged based on other medical conditions

DISTRIBUTION OF PATIENTS BASED ON CO-MORBIDITIES

24 patients (70.45%) and 13 patients (29.26%) of the 44 patients with co-morbidities were found to be male and female, respectively.

Table 5: Distribution of patients based on co-morbidities.

Gender	co-morbidities count	co-morbidities %
Male	31	70.45%
Female	13	29.26%

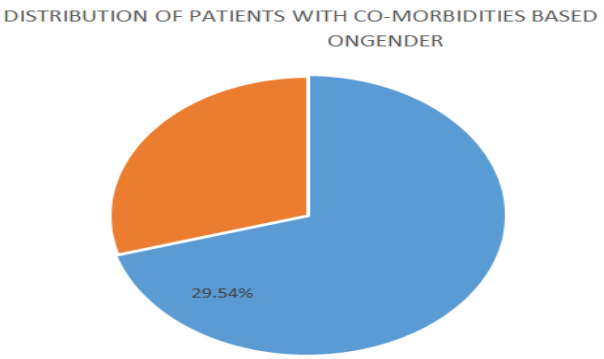


Figure: 5 - Distribution of patients based on co-morbidities.

PATIENTS WITH CO-MORBIDITIES DISTRIBUTED ACCORDING TOGENDER

Of the forty-nine male patients, eighteen had no co-morbidities; five had diabetes mellitus; two had hypertension; ten had diabetes plus hypertension; two had CAD; four had hypertensions plus thyroid; three had thyroid; and three had other co-morbidities.

Out of 19 female, 6 patients had no Co-morbidities, 2patients was having Hypotension, 3patients were having DM+HTN, 4patients were having PCOD, 2 patients was having DM, 3patients were having other Co-morbidities.

Table 6: Patients with co-morbidities distributed according to gender.

CO-MORBIDITIES	MALES	FEMALES
NORMAL	18	6
HYPERTENSION	2	0
HYPOTENSION	0	2
DIABETES MELLITUS	5	1
THYROID	3	0
PCOD	0	4
ASTHAMA	2	0
CAD	2	0
HTN + DM	10	3
HTN + THYROID	4	0
HTN + DM + THYROID	3	3

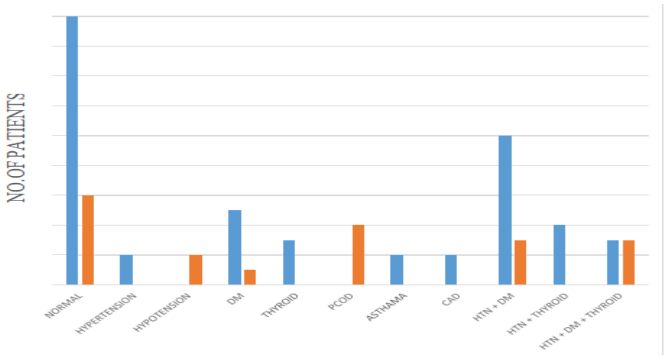


Figure: 6 - Patients with co-morbidities distributed according to gender.

DISTRIBUTION OF PATIENTS BASED ON TOTAL CO-MORBIDITIES

Out of 70 individuals, 30 patients had no Co-morbidities, 5 patients were having Diabetes mellitus, 2 patients were having Hypertension, 6 patients were having DM+HTN, 3 patients were having CAD, 2 patients were having PCOD, 5 patients were having AKI, 4 patients were having Hypothyroidism, 13 patients were having other Co-morbidities.

Table 7: Distribution of patients based on total co-morbidities.

CO-MORBIDITIES	TOATL PATIENTS	PERCENTAGE
NORMAL	24	35.29%
HYPERTENSION	02	2.94%
HYPOTENSION	02	2.94%
DIABETES MELLITUS	06	8.82%
THYROID	03	4.41%
ASTHAMA	02	2.94%
CAD	02	2.94%
PCOD	04	5.88%
HTN + DM	13	19.11%
HTN + THYROID	04	5.88%
HTN + DM + THYROID	06	8.82%

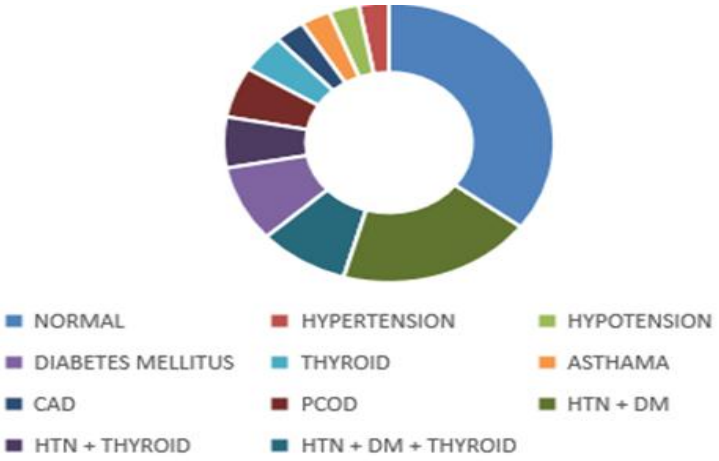


Figure: 7- Distribution of patients based on total co-morbidities.

DISTRIBUTION OF MALES BASED THEIR SOCIAL HISTORY

Ten patients out of the forty-nine males were found to be drinkers, two to be smokers, andeleven to be both.

Table 8: Distribution of males based their social history.

No – social history	alcoholic	smoking	Both alcohol and smoking
26 patients	10 patients	02 patients	11 patients

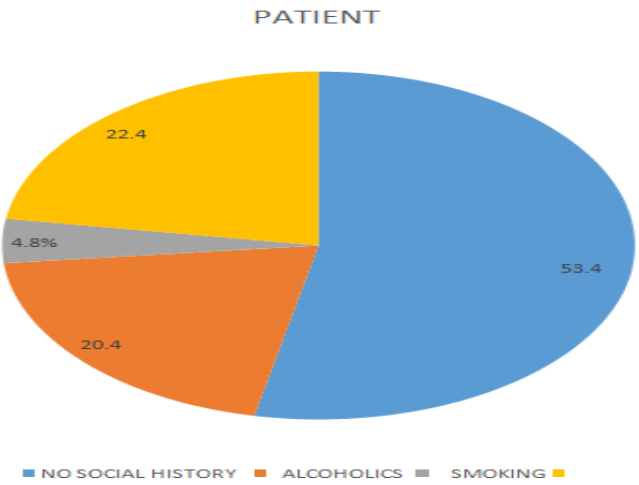


Figure: 8- Distribution of males based their social history.

DISTRIBUTION BASED ON TACROLIMUS LEVELS

53 patients out of the 68 patients received a prescription for tacrolimus; 5 patients (9.43%) haddrug concentrations that were below the normal range, and 48 patients (90.56%) had the targetplasma levels.

Table 9: Distribution based on tacrolimus levels.

Tacrolimus Levels	total no. of patients	percentage
0-5ng/ml (below normal)	5	9.43%
5-20ng/ml	48	90.56%

DISTRIBUTION BASED ON TACROLIMUS LEVELS

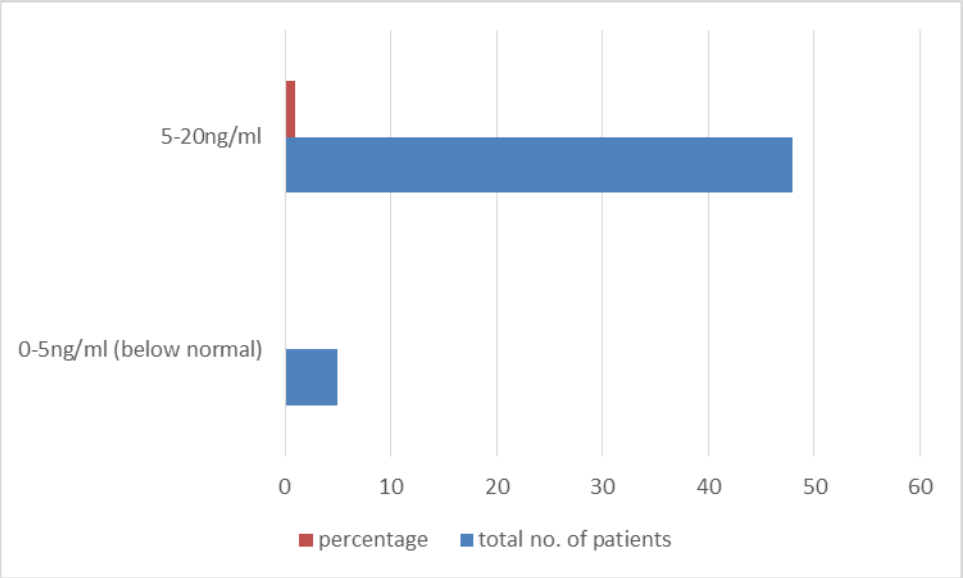


Figure: 9- Distribution based on tacrolimus levels.

DISTRIBUTION BASED ON CYCLOSPORINE LEVELS

Ten patients out of the 68 received cyclosporine treatment; eight (80%) of these patients achieved the required plasma concentration, and two (20%) of these patients did.

Table 10: Distribution based on cyclosporine levels.

Cyclosporine levels	Total No. of Patients	Percentage
0-100ng/ml (Below Normal)	2	20%
100-200ng/ml (Normal)	8	80%

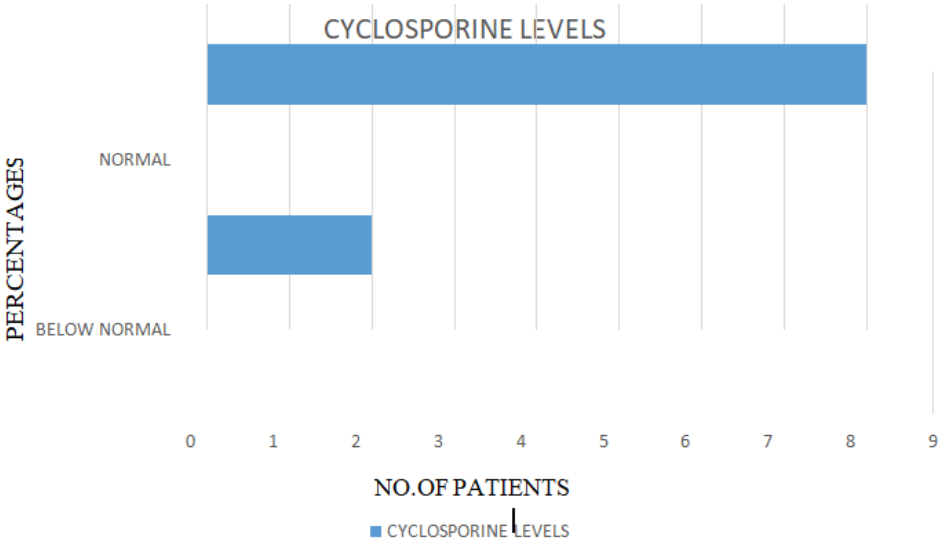
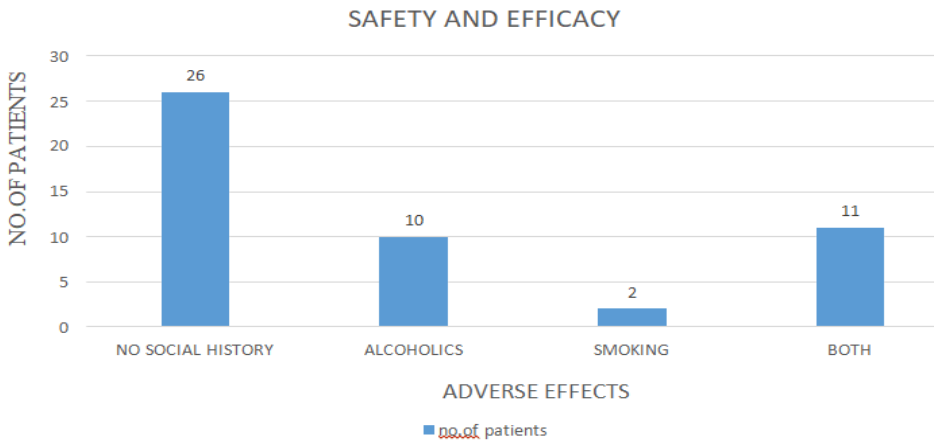


Figure: 10- Distribution based on cyclosporine levels.

SAFETY AND EFFICACY

The Safety results of medications used in liver transplantation which includes sample of 68 patients / participants /individuals are as follows Out of 68 patients involved in the study, 4 patients had experienced HTN, 3 bladder pain and 2 patients experienced SOB, 1 patient experienced confusion.



It is crucial to remember that the remaining 50 participants did not possess any side effects these finding from the safety results we provide an overview of safety results. We provide an overview of side effects such as HTN, BLADDER PAIN, SOB, and confusion. Being Observedin a small percentage of the sample. Finally, we can conclude that 55 patients had no side effects and even single patient has does not reported any graft rejection complaint. with this we conclude that these drugs have more efficacy.

DISCUSSION

In a tertiary care hospital, we conducted a prospective observational study with 68 participants to assess the safety and effectiveness of immunosuppressants throughout liver transplant recipients' hospital stays.

When the age groups were separated at intervals of 07, there were more male patients than female patients, with 49 of the 68 total patients identifying as men and 19 as women.

There were significantly more patients (20%) in the age group 0-10, and a lesser number of patients (4.40%) in the age range 11-20. Most patients (47.05%) were discovered in the age range 41-60.

44 patients (64.70%) and 24 patients (35.24%) out of 68 patients had co-morbidities.

In a total of 68 patients 23 patients have social histories and 45 patients has no social history.

Out of the three medications listed, tacrolimus has been prescribed for more patients (70%), cyclosporine for 20% of patients, and mycophenolate mofetil for 10% of patients.

The Safety results of medications used in liver transplantation which includes sample of 68 patients / participants /individuals are as follows:

Out of 68 patients involved in the study, 4 patients had experienced HTN, 3 bladder pain and 2 patients experienced SOB, 1 patient experienced confusion.

It is crucial to remember that the remaining 50 individuals did not have reported any side effects these finding from the safety results we provide an overview of safety results. We provide an overview of side effects such as HTN, BLADDER PAIN, SOB, and confusion. Being Observedin a small percentage of the sample. Finally, we can conclude that 55 patients had no side effects and even single patient has does not reported any graft rejection complaint. with this we conclude that these drugs have more efficacy.

CONCLUSION

The study was carried out in the Hepatology department for a period of 6 months. The number of samples collected were 68. Among 68 patients, 72.05% are Male and Female were 27.94%. The transplant typical cause was Cryptogenic. Diabetes and Hypertension are the two most frequent comorbidities identified in these patients.

Live liver transplants were carried out on each of the patients, who ranged in age from 41 to 60.

Patients receiving liver transplants were given immunosuppressants for the duration of their hospital stay. During the hospital stay, Tdms for immunosuppressants were monitored.

Overall, 70% of patients were prescribed Tacrolimus and 20 % of patients were prescribed cyclosporine and 10% of patients prescribed mycophenolate mofetil.

The safety and efficacy of the immunosuppressants is more by analyzing their adr's and thereis no single graft rejection in liver transplant patients. With these we can conclude that these drugs have more efficacy.

Finally, we can demonstrate that combination therapy had shown its effectiveness in liver transplantation patients.

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