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USE OF FIRST CE CERTIFIED INDIAN HEMODIALYSIS MACHINE RXT17 WITH REMOTE MONITORING IN A GOVERNMENT TERITORY CARE SETUP- KR HOSPITAL, MMC & RI, MYSORE

Nephrology

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ABSTRACT

Background: Dialysis technology has made huge strides. ESRD population is a major care pathway issue and fiscal conundrum for the country's health-care system. Driven by the need for cost-effective dialysis sessions, the number of public-private partnerships is on the rise. The dialysis equipment market world over, including India is currently led by manufacterers outside from India. Hence, a large gap exists for the domestic manufacturer to provide innovative, cost effective, made for India, high quality dialysis devices, consumables and service. Hence this study was done to measure the safety and eficacy of the Renalyx RxT17 hemodialysis machine manufactured by Bharath Electronics Limited for the dialysis therapy with the current standard of care for treatment of ESRD. **Objective:** The aim of study was to measure the safety and eficacy of the Renalyx RxT17 hemodialysis machine of the dialysis therapy with the current standard of care for treatment of ESRD. **Material And Methods** :A total of four subjects (patients) who underwent regular HD fifty session and who met the inclusion criteria were enrolled in the study. This is a prospective, open labelled, controlled study designed to provide the trial data of the Renalyx RxT17 conducted in government teritory care setup- KR Hospital, MMC & RI, Mysore.The patients were also monitored using a Telenephrology application to implement a remote care delivery model in addition to the conventional care. **Results** :The machine used in this study provided satisfactory dialysis to 4 patients (50 dialysis sessions). The safety of the machine was evidenced by the observation of no major alarms, optimal intra-session vital sign readings, no serious side effects during the trial period. The performance outcomes such as clearance of urea and creatinine, volume of ultrafiltration removed and stability of dialysate conductivity and temperature were acceptable.

KEYWORDS

HD (Hemodialysis),ESRD-End stage renal disease,Ultrafiltration, Conductivity.

INTRODUCTION

The 1940s saw the advent of the first dialysis in the United States. The first artificial kidney, was built in 1943 by Dr Willem Kolff, to clean the blood of a patient with acute kidney failure [1]. Dialysis technology has made huge strides since, and research has moved to enabling personalized wearable devices for the coming millions with ESRD [2]. India with over a 1.2 billion population, is projected to be a major future reservoir of non-communicable disease, especially diabetes and hypertension. Out of the 25-40% diabetics are likely to develop chronic kidney disease (CKD) in India, 10% will contribute to the burgeoning ESRD burden [3]. An ESRD prevalence figure of 100-250 per million population (pmp) per year is cited, based on worldwide estimates and local tertiary care centres research [4] [5] [6]. There is a need for cost-effective dialysis sessions. Hence, a large gap exists for the domestic manufacturer to provide innovative, cost effective, made for India, high quality dialysis devices, consumables and service

Material , Methods And Sample Size : A total of four subjects (patients) who underwent regular HD fifty session and who met the inclusion criteria were enrolled in the study. This is a prospective, open labelled, controlled study designed to provide the trial data of the Renalyx RxT17 conducted in government teritory care setup- KR Hospital, MMC & RI, Mysore. The patients were also monitored using a Telenephrology application to implement a remote care delivery model in addition to the conventional care.

Inclusion Criteria

1. Patient willing and competent to sign the approved informed consent.
2. Patients must be at least 21 years of age or older.
3. Patients must weigh between 40 and 100kg, inclusive.
4. Patients must have End Stage Renal Disease and currently undergoing consistent intermittent HD at least 2 times a week for at least 3 months prior to being enrolled.
5. Vascular access must be through a functioning arteriovenous fistula (AVF)/ Internal Jugular Catheter (IJC)/ Femoral catheter with no thrombolytic therapy or clotting of the AVF within the past 4 weeks.
6. Expected survival of no less than 6 months.
7. Consent to allow review of their medical records by the investigators, and monitors.
8. Hemoglobin level ≥ 8.0 g/dL prior to hemodialysis treatment.

Exclusion Criteria

1. Anticipating or scheduled for a living related donor kidney transplant in less than 2 months.
2. History (within the 12 weeks prior to the study) of cardiovascular events including.

a. Unstable angina
b. Myocardial Infarction
c. Stroke

3. Clinical Significant Arrhythmia.
4. Life threatening arrhythmia within the past 30 days.
5. Severe intra-dialytic hypotension within the last 30 days.
6. Shock within the last 30 days.
7. Hemodynamic instability as demonstrated by repeated episodes of hypotension or hypertension requiring intervention by dialysis personnel or representing a present hazard to the patient.
8. Seizure disorder requiring active treatment for a seizure episode during the last 6 months.
9. Major Surgery (excluding vascular access surgery) within the past 30 days.
10. Currently receiving intravenous antibiotic therapy for systemic infection.
11. Clinical evidence of metastatic malignancy, receiving radiation or chemotherapy, within the past 365 days.
12. Active bleeding.
13. Hematological disease (e.g. malignancies, hemolytic anemia, thrombocytopenia), and other conditions that may interfere with data.
14. Current enrollment in another investigational device or drug trial.
15. Subject is pregnant (e.g., positive HCG test) or is breast-feeding.
16. Subject has any disorder (excluding illiteracy or visual impairment) that compromises the ability of the subject to give written informed consent and/or to comply with the study procedures.
17. Allergy to heparin or ethylene oxide.
18. Hypertension deemed uncontrolled, at the discretion of the investigator, within the past 30 days.
19. Has an implantable electronic device (e.g. pacemaker).
20. Has no positive viral serology.

Study tools and data collection procedure:

A detailed history, clinical examination and required investigation were done.

Important invetigation done was pre and post dialysis blood urea estimation to calculate Urea reduction rate and hence derive at Ktv value.

Statistical analysis All data pertinent to the patients are obtained and the analysis of efficacy in terms of conductivity, temperature, ultrafiltration, dialysis dose, urea reduction ratio (URR) were analyzed using the Student's paired T test, with a $p <= 0.05$ will be considered statistically significant, with the inclusion of tolerance limits for pertinent variables. In relation to machine performance the dialysate conductivity and temperature data were analyzed. Ultrafiltration, dialysis dose and urea reduction ratio (URR) were analyzed to evaluate dialysis efficacy.

RESULT :

The average age of all the 4 patients was 50 ±15 years, with average weight of 50 ±15 Kg. All of the patient related clinical characteristics were found to be with the normal range during the entire trial. A total of 50 dialysis sessions were conducted at the dialysis unit, KR Hospital, MMC & RI, Mysore. Each session lasted for approximately 4 hours. The blood flow ranged between (150 mL/min and increased to a maximum of 300mL/min). The dialysis flow rate was fixed at 500mL/min. All patients completed the study.

The machine performed satisfactorily in terms of the efficacy endpoint: achieving ultrafiltration goal, maintaining temperature and conductivity (under relevant tolerance limits). All machine data measured were within the acceptable ranges of conductivity (Sodium equivalent of less than 3 mEq/L), temperature (±0.5°C of set), and set ultrafiltration (UF) volume (within 10%) of target value.

Dialysate conductivity is a suitable parameter to measure the concentration of salts present in the dialysate solution. This is critical in maintaining and managing the electrolyte equilibrium between the dialysate and blood. During the sessions the conductivity was set at 14 mS/cm, with an alarm range between 13.5 mS/cm and 14.5 mS/cm. The statistical mean dialysate conductivity was mS/cm.

Table 1: Dialysate Conductivity

Dialysate Conductivity		
Machine type	Mean (mS/cm)	Standard Deviation
RxT17 HD	13.86	0.08

Dialysate temperature during treatment should be selected to maintain homeostasis without triggering any physiological defense mechanisms. During the sessions the temperature was set at 37°C, with an alarm range between 35.9°C and 38.1°C. The results are tabulated for the Renalyx RxT17, throughout the study .

Table 2: Dialysate Temperature

Dialysate Temperature		
Machine type	Mean (ºC)	Standard Deviation
RxT17 HD	37.00	0.07

Ultrafiltration during dialysis is the removal of fluids from the patient. The target ultrafiltration goal is set in the machine according to the post dialysis weight that needs to be achieved. The removed ultrafiltration value is the difference between the patient's pre dialysis weight and post dialysis weight. Lesser the variation between the target ultrafiltration goal and the ultrafiltrate removed the better the dialysis efficacy.

Table 3: Ultrafiltration difference

Ultrafiltration difference (Target - Removed)		
Machine type	Mean (mL)	Standard Deviation
RxT17 HD	1046.77	587.50

Urea reduction ratio was greater than 60%

Safety Results

The patient safety requirements were documented in terms of any adverse events/ serious adverse events that could potentially arise and harm the patient. Moreover, alarms to recognize any potential harm were in place and appropriate alarms were raised that helped to mitigate the underlying problem. During the sessions the patient's blood pressure was regularly monitored, no intradialytic hypotensive episodes were observed (a drop in systolic and diastolic pressure below 100 and 60 mm of Hg, respectively). Patients have not reported any other side effects/ adverse events in all the 50 dialysis session.No serious device deficiencies were observed during the dialysis sessions All the patients responded to the Renal Treatment Satisfaction questionnaire . 100% positive response, suggesting that they were very satisfied with dialysis therapy for the Renalyx RxT 17 machine.

DISCUSSION

The End stage renal disease (ESRD) incidence rates stand at 151 and 232 per million populations, respectively in India. All of the current hemodialysis machines used in India are imported at significantly high costs, which further increases the cost of treatment. Therefore, through the application of the indigenously developed hemodialysis machine RxT17 could bridge the gap, a step further.

The ease of the device is made simple through the on-screen user interface section. The step-by-step instructions enable a technician or trained nurse to handle the machine effortlessly. The highlights of safety and machine performance aspects of the device operate akin to Reference Dialysis Machine. These outcomes in general encompass the needs of a normal hemodialysis.

With less than 2600 registered nephrologists, India has one of the lowest nephrologist to patient ratios in the world [11].. This gap can be addressed by the telenephrology based rural care delivery model.

The use of the cloud-based Telenephrology and Nephrology Information System (NIS) allows for the real time monitoring of the dialysis session and patient condition. It receives data from the Renalyx RxT 17 dialysis machine that allows the monitoring of alarms, dialysis run time, UF removed, rates, temperatures etc. This data can be viewed either through a web browser or using the android mobile application. Thereby, enabling clinicians in the main dialysis centre, JSS Mysuru (Hub) to regularly monitor patients at JSS Chamarajanagar (Spoke). NIS allows the clinicians in the 'Hub' to regularly assess patient dialysis treatment and intervene and guide the technicians in the 'Spoke', during dialysis. Subsequently, the nephrologist can update the dialysis prescription and prescribe laboratory tests and medication to the patient.

CONCLUSION

The indigenously developed Renalyx RxT17 machine along with telenephrology feature (Nephrology Information System - Web & Android applications) provided satisfactory dialysis to 4 patients (50 dialysis sessions) on regular hemodialysis while allowing the doctors to monitor patients continuously from remote areas. The safety of the machine was evidenced by the observation of no major alarms, optimal intra-session vital sign readings, no serious side effects during the trial period. The performance outcomes such as clearance of urea and creatinine, volume of ultrafiltration removed and stability of dialysate conductivity and temperature were acceptable.

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