ABSTRACT

Background: End stage renal disease (ESRD) is an irreversible deterioration of kidney normal function (GFR <15 mL/min/1.73 m²) and requires renal replacement therapy. The hemodialysis (HD) patients have typically multiple comorbidities and have a huge burden of prescription medicines and polypharmacy. The Health-Related Quality of Life (HRQoL) is an important measure in the HD often compromises with the patient’s ability to earn affecting financial income. The HD patients with economic burden, dependency along with the morbidity of the disease are likely to feel negative and depressive.

Methodology: Open label Randomized control trial was carried out at 3 different HD centres of teaching, government and corporate hospitals. The patients were randomised into two groups [Usual Care Group (UC) and Pharmaceutical Care Group (PC)] by the block design method. The PC group received the normal care along with pharmaceutical care delivered by a qualified registered pharmacist. The customized care plan was designed and delivered to the patients on monthly basis based on the condition and need of the patient by WHO-FIP Pharmaceutical care model. The primary outcome of the study is HRQoL and the secondary outcomes include Hemoglobin levels, Interdialytic weight gain (IDW), Blood pressure (BP), Medication adherence and expenditures. The assessment was done at baseline, 6th and 12th months by follow-upping both the groups for a total period of 12 months.

Results: The intervention of pharmaceutical care significantly improved the HRQoL scores over a period of time in the domains noticed with regard to the “physical functioning, general health, emotional well-being, social functioning, symptom/problem list and effects of kidney disease” in all the three centres of PC group compared to UC group with p value < 0.05. The PC group had significantly reduced its IDW and BP levels in comparison to UC group at different time intervals. The hemoglobin levels and medication adherence rate scores of HD patients were significantly increased in PC group compared to UC group at different time intervals with a statistically significance of p < 0.05 in academic hospital, government hospital and cumulative data of HD patients. The PC group had an Incremental Cost Effective Ratio (ICER) of 86230 INR / Quality-Adjusted Life Year (QALY) gained, 231016.66 INR / QALY gained, 87430 INR / QALY gained and 51340 INR / QALY gained for academic, government, corporate hospitals and cumulative HD patients’ data respectively.

Conclusion: The ‘WHO-FIP pharmaceutical care’ plan model delivered by the registered pharmacist regarding the knowledge about disease, medications, life style changes, nutritional information, personal interview and medication review had positive impact on the HRQoL, clinical and QALY outcomes. In the present study, the cost per QALY of the HD patients is less than 3 times the annual GDP per capital of the country which is considered as cost-effective. It was also suggested that an extra cost is required for each additional QALY gained to choose alternative pharmaceutical care over usual care.