The Effect of Pharmacist's Interventions on Anaemia Management among Continuous Ambulatory Peritoneal Dialysis Patients in Terengganu Tertiary Hospital

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ABSTRACT

Pharmacist's interventions in anaemia management have been shown to improve clinical and economic outcomes. To determine the outcome of hemoglobin (Hb) level after the implementation of ESA monitoring card and counselling, a prospective, single-blinded randomised controlled study involved patients attending the CAPD clinic in Terengganu tertiary hospital, Malaysia was carried out. Intervention group received ESA injection counselling based on a validated checklist and ESA monitoring card, while the standard care group only received standard care. Result showed a total of 118 eligible patients with 68 of them in the standard care group and 50 patients in the intervention group with an average age of 50.8 (± 14.57) and 49.4 (± 13.69) years, respectively. Mean Hb showed significant improvement in both standard care and interventional groups with $p < 0.001$. Intervention group had a higher percentage increment in mean Hb 6.7% compared to standard care group 5.9%. However, mean difference Hb between standard care and interventional group after at least 1 month of interventions was not significant with 0.59 (± 1.78) and 0.692 (± 1.68) respectively ($p = 0.764$). In conclusion, pharmacist's interventions, including counselling and ESA monitoring card may help in improving Hb level in CAPD patients.

INTRODUCTION

Anaemia is a common complication among chronic kidney disease (CKD) patients and, its prevalence rises with decreasing estimated glomerular filtration [1]. Anaemia in CKD presents as normochromic, normocytic and associated with symptoms such as fatigue, shortness of breath, insomnia, and headache [2]. Inadequate erythropoietin production is the most common cause of anaemia [1–3]. It contributes to reduced quality of life and is associated with cardiovascular disease, hospitalisation, cognitive impairment, and mortality [4].

Erythropoietin stimulating agent (ESA) and iron supplementation are the standard treatment for anaemia among end stage renal failure (ESRF) patients in Malaysia. Each patient is treated according to the haemoglobin (Hb) target with the lowest effective ESA dose while avoiding large fluctuations

in Hb levels or prolonged periods out of target Hb [5]. Studies have shown the beneficial effects of anaemia treatment, such as improved quality of life protection against cardiovascular disease, morbidity, mortality, and hospitalisation rates reduction [6]. However, anaemia management in ESRF patients is complex, and there are barriers to effective anaemia treatment, including patient non-adherence to the treatment regimen, lack of familiarity with clinical practice guidelines for anaemia treatment, and complexity of patients with CKD [7]. In addition, managing renal anaemia with ESA and iron replacement poses clinical challenges, including maintaining stable Hb levels within narrow target ranges, balancing iron and ESA dosages, and optimising the erythropoietin response with the lowest possible effective ESA dose [8]. Therefore, a multidisciplinary approach is necessary to overcome the challenges and barriers in anaemia treatment. Pharmacist clinical activities in anaemia management, including providing

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²Department of Nephrology, Hospital Sultanah Nur Zahirah, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Terengganu, Malaysia.

drug information to the physician, compiling guidelines for proper use of ESA and iron, dosing and monitoring ESA therapy, patient education had effectively improved Hb level, and compliance with ESA use criteria [8–10].

The effectiveness of a treatment depends on patient adherence and proper ESA injection technique. Inadequate knowledge on ESA injection can influence patient medication adherence. However, we have limited data on patient medication knowledge and ESA injection technique. Besides, one of the key performance indicators (KPI) in our nephrology department is that at least 70% of continuous ambulatory peritoneal dialysis (CAPD) patients achieved the target Hb level (10g/dl), but we did not meet the KPI to date. Despite renal pharmacists have been part of renal team and participate in the treatment of CKD, there is no relevant study on the effectiveness of renal pharmacy service in Malaysia. Therefore, we would like to investigate the effectiveness of interventions by pharmacists in optimising anaemia management in CAPD patients. The main objective of this study was to investigate the effect of pharmacist interventions on Hb outcome in CAPD patients receiving subcutaneous (SC) ESA.

METHOD

Study Design and Setting

This is a prospective, single-blinded randomised controlled study. The study was conducted for 6 months in the CAPD clinic of Terengganu tertiary hospital, Malaysia. The recruitment and data collection was performed from March to August 2017. The setting for pharmacist educational intervention consisted of a private counselling room in the CAPD clinic. The study was approved by Medical Research and Ethics Committee, Ministry of Health Malaysia (MOH) Malaysia (KKM.NIHSEC.P17-1202). Informed consent was obtained from all individual participants included in the study.

Participants and randomisation

Based on the study done by Wei Yang et al., the sample size required for detecting difference of mean Hb is 0.5g/dl with power of study =80%, and type 1 error at 0.05 was 48 subjects for both intervention group and standard care subjects [11]. A total of 55 subjects for each arm were included in this study by considering a dropout rate of 10%. Participants randomised into the interventional group and standard care with a 1:2 ratio using simple randomisation technique. For the allocation of the participants, a list of all CAPD patients was created in the software of SPSS Version 22 by one pharmacist and then a randomisation sequence was created using this computer-generated list of numbers into both interventional and control groups. Three pharmacists involved in patient enrollment.

Patient did not know which group they are in as this is a single-blinded study.

Research tool

- ESA monitoring card initiative from the MOH Malaysia to properly monitor Hb level in dialysis patients with ESA therapy. Physician updated the latest Hb level and ESA dose on the ESA card for each appointment. ESA card consists of ESA dose titration and monitoring parameter guidelines developed based on KDIGO clinical practice guideline for anaemia in CKD 2012 to assist the physician in adjusting ESA dose and monitoring. Adjustment of ESA dose was based on patient current Hb level, rate of change in Hb concentration, current ESA dose and clinical circumstances [12]. ESA monitoring card is attached as Appendix 1.
- Counselling checklist for ESA injection initiative from MOH Malaysia is intended as a reference document for pharmacist or nursing staff to counsel patients prescribed with ESA. Counselling checklist is attached as Appendix 2.
- Data collection form was used to collect information regarding the patient's social demographic data, medical history, current ESA dose, current medications, laboratory parameters, and medication adherence. We included CAPD patients above 18 years old who attended CAPD clinic, received SC erythropoietin beta injection and been taught on ESA injection technique by CAPD nurse. Excluded patients including who received blood transfusion two weeks before recruitment and within the study period; pregnant patient and cancer patient.

Standard care

The standard care of patients consisted of physician-patient meetings in the CAPD clinic. Patients who are newly prescribed ESA injection referred to CAPD nurse for ESA injection technique related education. Patients collected their monthly ESA injection from the hemodialysis unit and self-injected ESA at home. Patients in the standard care group did not receive intervention from pharmacists.

Intervention

Patients in the intervention group received standard care of physician-patient meetings and pharmacist interventions. Intervention group patients were required to attend hospital at the baseline, three months, and six months during the intervention. Patients' follow-up visits were arranged according to patient-physician appointment to reduce dropout. At the baseline visit, demographic data; current medication; current

ESA dose; laboratory parameters such as Hb level, iron status, serum ferritin, TSAT, and TIBC level were collected. On each follow-up visit, patients were assessed on ESA injection knowledge based on ESA counselling checklist, including its function, dose of injection, side effects, storage, and ESA transport from hospital to home, injection technique and adherence. Patients were required to answer all questions in ESA checklist correctly; any wrong answer given was considered inadequate knowledge. Pharmacists provided counselling and education for patients with inadequate knowledge or wrong injection techniques to improve their knowledge or injection technique. Monitoring of laboratory parameter and ESA dose were performed, and any intervention was spoken to the nephrology physician.

Outcome measures

Primary outcome of the study was Hb level. The target Hb in our setting is 10-12g/dl. Monitoring of Hb level, iron status, serum ferritin, TSAT, TIBC level was performed every 3 months as recommended by Kidney Disease Improving Global Outcome (KDIGO) anaemia guideline for CKD 2012.

Secondary outcome of the study was the adherence to ESA injection post-intervention. Adherence to ESA injection was assessed based on the ESA sticker. The patient was required to detach the sticker from the ESA injection syringe before use and paste it on the CAPD booklet as evidence of use. Pharmacists calculated the number of ESA injections dispensed for the patient last month and the total number of stickers found on the CAPD booklet. The total doses missed was inferred from the sticker count observed from the CAPD booklet. A patient is defined as adhering to ESA injection if the adherence score (Eq.1) is $\geq 90\%$ [13].

$$\text{Adherence score} = \frac{\text{Total doses dispensed} - \text{Total dose missed}}{\text{Total dose dispensed}} \quad (\text{Eq. 1})$$

Data analyses

All data were analysed using IBM® Statistical Package for Social Sciences version 22.0 (IBM corp. 2013). Baseline characteristics of both groups were compared using Independent t-test for continuous variables, Person chi-square, and Fisher-exact for categorical variable. Comparison of mean difference in Hb was performed using Independent t-test and Paired t-test. All statistical tests with p-values of <0.05 denote statistical significance.

RESULT

Demographic and Clinical Characteristics

Of the 146 eligible patients, 50 patients were randomised to the intervention group, and 70 patients were randomised into the standard care group. 2 patients dropped out of the study due to deceased. A total of 118 patients completed the study. Figure I. shows the trial flow diagram prepared according to CONSORT guidelines. The average ages were 50.8 (± 14.57) and 49.4 (± 13.69) years in the standard care and interventional groups. Gender was found to be approximately equal, and subjects were predominantly Malay in both groups. Details of patient characteristics are shown in Table I. There was no significant difference in the baseline demographic and clinical characteristics of participants.

Figure I. Trial flow diagram in accordance with CONSORT guidelines

Table I: Demographic data and clinical characteristics (N=118)

Characteristics	Standard Care Group (n = 68)	Interventional Group (n=50)	P-Value*
Age, mean (SD), year	50.8 (14.5)	49.4 (13.6)	0.593
Gender, n (%)			
Male	34 (28.8)	23 (19.6)	0.404a
Female	34 (28.8)	27 (22.8)	
Ethnicity, n (%)			
Malay	68 (57.6)	49 (41.6)	0.347b
Chinese	0	1 (0.8)	
Body weight, mean (SD), kg	60.9 (13.8)	60.7 (12.5)	0.957
Transferrin saturation, mean (SD), %	30.7 (13.4)	29.3 (10.3)	0.541

*Independent t-test, ^a Pearson chi-square, ^b Fisher-exact tests were used

Hb level in pre-and post-intervention for standard care and interventional groups

Mean Hb showed significant improvement in both standard care and interventional groups with $p < 0.001$ (Table II). The intervention group had a higher increment in mean Hb (6.7%) than the standard care group (5.9%). However, the mean difference Hb between standard care and interventional group after at least one month of interventions was found to be not significant with 0.59 (± 1.78) and 0.692 (± 1.68) respectively ($p = 0.764$) using Independent T-test (Table III).

Adherence to ESA administration post-intervention for standard care and interventional groups

The intervention group had higher adherence to ESA administration (76%) than the standard care group (66.1%) post-intervention. No significant difference was found between the standard care and intervention group ($p = 0.309$) using Chi-square test (Table IV).

Table II. Mean Hb of pre and post-intervention for standard care and interventional group

Characteristic	Pre intervention mean Hb (SD), g/dL	Post interventions mean Hb (SD), g/dL	CI	P-Value*
Standard Care Group (n = 68)	9.84 (± 1.89)	10.44 (± 1.91)	-1.02, -0.16	<0.001
Interventional Group (n=50)	9.74 (± 1.68)	10.43 (± 1.90)	-1.17, -0.21	<0.001

*Paired t-test was used

Table III. Mean difference Hb for standard care and interventional group

Characteristic	Mean difference Hb (SD), g/dL	CI	P-Value*
Standard Care Group (n = 68)	0.594 (± 1.78)	-0.74, 0.54	0.764
Interventional Group (n=50)	0.69 (± 1.68)	-0.73, 0.54	

*Independent t-test was used

Table IV. Adherence to ESA administration between both groups

Characteristic	Yes (n, %)	No (n, %)	P-Value*
Standard Care Group (n = 68)	45 (66.1)	23 (33.9)	0.309
Interventional Group (n=50)	38 (76)	12 (24)	

*Chi-square test

DISCUSSION

Severe anaemia ($Hb < 9.0$ g/dL) is associated with increased risks of cardiac complications, such as left ventricular hypertrophy and cardiovascular disease, and low quality of life [14]. Correction of anaemia has been associated with improved health-related quality of life, including physical functioning and fatigue [15]. With the increasing health care cost over the past several years, pharmacists have a critical role in providing the most cost-effective and beneficial pharmaceutical care in anaemia treatment. Available studies reported the benefits and impact of pharmacy services in anaemia management. A study conducted showed that active participation of pharmacists in anaemia management significantly improved mean Hb level [8,16]. Other studies reported that pharmacist education program led to significant Hb improvement. [17,18].

Our study demonstrated that intervention group showed significant improvement in mean Hb, but the mean difference Hb was statistically non-significance against the standard care group. Likewise, previous studies also did not show significant differences in haemoglobin outcome between standard care and pharmacist intervention group [10,18]. The lack of significance was explained by achievement of haemoglobin target was very high in standard group compared with other studies [10]. Study by Mateti et al. reported that the insignificant result was due to both control and intervention group had achieved the optimal Hb level of 10g/dL, and increasing the target Hb above the target range had no benefit [18]. In our study, the insignificant result could be due to lack of blinding in pharmacist activities such as counselling and ESA card, which may increase overall patient care by healthcare providers. Besides, similar physicians who attended patient's follow-up visits in both control and interventional groups may lead to bias. Deficiency of vitamin B12, folic acid, and iron are associated with anaemia [12]. Adherence to oral iron and different dietary intake could be factors affecting haemoglobin level. However, our study lacks data on patient adherence to oral iron and dietary pattern, so a definite conclusion cannot be drawn.

ESA injection adherence compliance was a common problem in peritoneal dialysis patients. Peritoneal dialysis patients are generally taught to self-administered SC ESA at home. Two studies showed that adherence rates with self-administered ESA ranged between 45% and 65% (non-adherence defined as less than 90% use of prescribed dose) [13,19]. This low percentage revealed the difficulty of PD patients to adherence with this treatment. In our study, we assessed patient adherence to ESA administration post-intervention. The result showed that the intervention group had a higher percentage of adherence to ESA administration than the standard group; however, there was no significant difference between the groups. Medication teaching emphasising patient adherence is an area in which pharmacists can positively affect patient care.

Educational interventions by pharmacists had significantly improved hemodialysis patients medication knowledge and medication adherence [20,21]. One study reported that pharmacist educational programme consisting of medical and therapeutic information, information on injection device, training of pen, self-injection of the first dose in front of pharmacists resulted in a higher level of adherence and leading to optimal Hb level within 2 months [17]. These strengthen the importance of patient education and medication teaching by pharmacists to improve adherence, achieve patient self-care, and attain therapeutic goals. However, this study has limitations. First, a short duration of the study was a limitation to draw a conclusion about the service's long-term effectiveness or to assess the clinical impact of the service. Besides, this was a single institutional study, and the result may not be generalisable to other practice settings. Future studies with similar design can be conducted at multiple centres to produce more reliable and generalisable results.

CONCLUSION

Pharmacist's interventions, including ESA injection counselling and ESA monitoring card may help in improving Hb level of CAPD patients.

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CONFLICT OF INTEREST

Authors declared no conflict of interest.

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Appendix 1

ESA monitoring card

Erythropoietin Stimulating Agent (ESA) Monitoring Card

Name : Age :
 MRN / IC No. : Gender : Male / Female
 Date of started ESA :
 Date of started CAPD : Counselling : ☐ Yes ☐ No

No. of Visit	Date	Hb Level (g/dL)	Dose (unit)	Remark(s)**
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

**ADR detected, change in brand etc

Target Hemoglobin Range: 10-11.5 g/dl (subjected to change according to the latest

Appendix 2

COUNSELLING CHECKLIST FOR ERYTHROPOIETIN STIMULATING AGENTS

This checklist is intended as reference document for use by pharmacist and/or nursing staff to counsel EVERY PATIENT who are prescribed with Erythropoietin Stimulating Agents (ESA_s). The completed counselling form should be kept in the respective patient file and/or pharmacy counselling folder for future reference.

NAME:

UNIT:

NAME:	UNIT:		REMARKS										
YES	NO												
1.	<p>What is EPO & why it is important to you?</p> <p>Erythropoietin is a hormone produced by healthy kidney. It is importance to produce red blood cells. When kidney fail, the production of erythropoietin is reduced. Hence you need to inject erythropoietin to maintain your haemoglobin level between 10-11.5g/dl</p> <p>*Target Hb may be changed according to latest evidence.</p>												
2.	<p>What EPO has doctor prescribed for you?</p> <p>The erythropoietin that the doctor has prescribed for you is</p> <p>Dose / frequency/ timing ESA</p> <p>~.....units.....time(s) a week/month.</p> <p>Inject preferably at the same time on the day at the schedule day</p>												
3.	<p>Possible/ common side effects of ESA</p> <p>Experiencing side effects from medications is not unusual. Side effects from ESA is generally not serious. The commons one are:</p> <ul style="list-style-type: none">- irritation at site of injection- headache- Joint / muscle pain- High blood pressure <p><i>NOTE: BP cut off point for ESA administration is individualised for each patient. Generally ESA withheld if BP >160/100 mmHg. Patient has to be informed on their BP cut off point to either withhold or continue ESA at home.</i></p>												
4.	<p>What can you do if you experience side effect that you cannot tolerate?</p> <p>Seek advice from the outpatient department pharmacy or dialysis unit</p>												
5.	<p>Storage & transport ESA from hospital to home</p> <ul style="list-style-type: none">- Transport of ESA is only allowed in cool box with ice packs- Preferably to return home immediately after you get ESA from pharmacy to facilitate fast storage.- ESA is very sensitive to light and temperature <p>Protect ESA from light</p> <p>Store ESA in refrigerator, do not freeze. Keep in 2-8 degree celcius. Avoid fridge door, and vegetable compartment. Ensure there is proper air circulation around your ESA.</p>												
6.	<p>Preparing your ESA before injection</p> <p>Do not take out your ESA from fridge UNLESS it is time for use. If you have accidentally left your ESA outside the fridge, it must be used ASAP before the ESA is damaged.</p> <table><thead><tr><th>Product</th><th>Maximum period before damage once out from the fridge</th></tr></thead><tbody><tr><td>Recormon</td><td>3 Days</td></tr><tr><td>Binocrit</td><td>3 Days</td></tr><tr><td>Mircera</td><td>1 month</td></tr><tr><td>Eprex</td><td>7 Days</td></tr></tbody></table>			Product	Maximum period before damage once out from the fridge	Recormon	3 Days	Binocrit	3 Days	Mircera	1 month	Eprex	7 Days
Product	Maximum period before damage once out from the fridge												
Recormon	3 Days												
Binocrit	3 Days												
Mircera	1 month												
Eprex	7 Days												
7.	<p>How to use injection</p> <p>Please refer to section B and C</p>												

Section B and C : Injection Technique for Recormon and Mircera

B	INJECTION TECHNIQUE FOR SUBCUTANEOUS RECORMON	Done (✓)
1.	Remove one syringe and check that the solution is clear, colourless and free from visible particles.	
2.	Allow Recormon to reach room temperature.	
3.	Wash your hand.	
4.	Remove the cap from the syringe.	
5.	Remove one needle from the pack, fix it on the syringe and remove the protective cap from the needle.	
6.	Expel air from the syringe and needle by holding the syringe vertically and gently pressing the plunger upwards.	
7.	Clean the skin at the site of injection using an alcohol wipe.	
8.	Form a skin fold by pinching the skin between thumb and forefinger.	
9.	Insert the needle into the skin fold with a quick, firm action.	
10.	Inject Recormon solution.	
11.	Withdraw the needle quickly and apply pressure over the injection site with a dry, sterile pad.	
12.	Dispose the empty syringe in special wastes container.	

C	INJECTION TECHNIQUE FOR SUBCUTANEOUS MIRCERA	Done (✓)
1.	Remove one syringe and check that the solution is clear, colourless and free from visible particles.	
2.	Allow Recormon to reach room temperature.	
3.	Wash your hand.	
4.	Remove the cap from the syringe.	
5.	Remove one needle from the pack, fix it on the syringe and remove the protective cap from the needle.	
6.	Expel air from the syringe and needle by holding the syringe vertically and gently pressing the plunger upwards.	
7.	Clean the skin at the site of injection using an alcohol wipe.	
8.	Form a skin fold by pinching the skin between thumb and forefinger.	
9.	Insert the needle into the skin fold with a quick, firm action.	
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11.	Withdraw the needle quickly and apply pressure over the injection site with a dry, sterile pad.	
12.	Dispose the empty syringe in special wastes container.	