

Quality Control of the Fluids Utilized in Dialysis with the Study of the Hemodialysis Status in Khartoum State

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Abstract—

Background: In this random quality control trail of the laboratory analysis of the fluids utilized for kidney failure patients, we aimed to reevaluate (analysis) of the compatibility of current fluids used in dialysis and the possibility of introducing other methodology and analysis to improve the dialysis and reduce morbidity and mortality rate.

Methods: The fluids analysis will performed mainly by atomic absorption spectroscopy, UV.VIS spectroscopy, HPLC, and Thin layer chromatography but we use more developed method, the atomic emission ICP device, and we took the hardness, specific gravity, PH and Pyrogen free test as a physical test of post treatment water to compare it with the standards stated by Fresenius company for the ideal processed water should use in the dialysis. Also a descriptive cross-sectional study design, Khartoum state 303 patients were selected randomly from 5 dialysis centers and interviewed using a questionnaire.

Results : In the analysis of the concentrated acid when all element turned by percentage most of the results were in the range of (100%, ± 5) with some exceptions in some elements as with potassium the samples are all high, in police hospital ,Soba hospital ,ebnouf hospital, Khartoum hospital and Salma hospitals potassium was 108.8%, 113%, 105.6%, 106.9% and 108% respectively. calcium and sodium was at the range in all hospitals also magnesium was in the range although it was relatively low in the analysis of the processed water and with the range of the standard company, PH of all hospitals water was found within the range except Alshaheeda Salma was found to be 8.48 (range from 6.5 to 7.5), The specific gravity is approximately 1gm/ml, in all hospitals (stated water specific gravity), and the hardness of all was found to be less than 0.2 mmol/l as wanted except Ebnouf hospital which was found 1.2620 mmol/l. The pyrogen free test (present absent test) revealed presence of spore forming bacteria in both of Alshaheeda salma and Khartoum hospital. The bicarbonate salt titration analysis revealed an acceptable percentage of the sodium bicarbonate.

Conclusion: Our conclusion is that the current status of dialysis is not as required as such the fluids used need to be reviewed. Great effort were done to improve the disease status, but still need more care as had been thoroughly investigation in this aspect.

Keywords— Hemodialysis, specific gravity, Hardness, quality control.

I. INTRODUCTION

Hemodialysis is a critical care medical technique which sustains the lives of thousands of patients who suffer from acute or chronic kidney failure. However, due to the inherent complexity and risk of the technique, a few patients experience adverse events which are avoidable. Most adverse events are caused by user error or a combination of user error and medical device malfunction.¹ A comprehensive device quality assurance program would help avoid many of these adverse events. The ISO definition of quality: "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs" Also quality can be defined as "delivery of reliable information within an agreed span of time under agreed conditions, at agreed costs, and with necessary aftercare"².

Hemodialysis:

Hemodialysis is the most common method used to treat advanced and permanent kidney failure. Hemodialysis is a

complicated and inconvenient therapy that requires a coordinated effort from the whole health care team, including the nephrologists, dialysis nurse, dialysis technician, dietitian, and social worker³⁻⁴. The most important members of the health care team are the patient itself and his\her family. By learning about the treatment, they can work with their health care team to give themselves the best possible results, and they can lead a full, active life⁵.

How Hemodialysis Works

In hemodialysis, your blood is allowed to flow, a few ounces at a time, through a special filter that removes wastes and extra fluids. The clean blood is then returned to your body. Removing the harmful wastes and extra salt and fluids helps control your blood pressure and keep the proper balance of electrolytes. Hemodialysis should be performed upon specific schedule and it should be monitored by your doctor and should be adjustment with your body needs in a hospital or a health care center.

Several centers around the countries teach people how to perform their own hemodialysis treatments at home. A family

member or friend who will be the patient helper must also take the training. Home dialysis gives more flexibility in the dialysis schedule. With home hemodialysis, the time for each session and the number of sessions per week may vary, but patients must maintain a regular schedule by giving themselves dialysis treatments as often as they would receive them in a dialysis unit⁶⁻¹³.

One important step before starting hemodialysis is preparing a vascular access, a site on the body from which blood is removed and returned. A vascular access should be prepared weeks or months before starting dialysis. It will allow easier and more efficient removal and replacement of blood with fewer complications. Even in the best situations, adjusting to the effects of kidney failure and the time patients spend on dialysis can be difficult. Aside from the “lost time,” they may have less energy. They may need to make changes in their work or home life, giving up some activities and responsibilities. Keeping the same schedule they kept when their kidneys were working can be very difficult now that their kidneys have failed. Accepting this new reality can be very hard on them and their family. A counselor or social worker can answer their questions and help they cope.

Many patients feel depressed when starting dialysis, or after several months of treatment. If they feel depressed, they should talk with their social worker, nurse, or doctor because this is a common problem that can often be treated effectively.

II. METHODOLOGY

The fluids analysis will performed mainly by atomic absorption spectroscopy, UV.VIS spectroscopy, HPLC, and

Thin layer chromatography but we use more developed method, the atomic emission ICP device , and we took the hardness, specific gravity , PH and Pyrogen free test as a physical test of post treatment water to compare it with the standards stated by Fresenius company for the ideal processed water should use in the dialysis. Also a descriptive cross-sectional study design, Khartoum state 303 patients were selected randomly from 5 dialysis centers and interviewed using a questionnaire.

III. RESULTS AND DISCUSSION

Quality Assurance in renal care covers a wide range of areas and applications. Some of these include, monitoring appropriateness of therapy; analysis of resource utilization and pursuing resulting necessary adjustments; assessing patient satisfaction; measuring morbidity and mortality with the subsequent implementation of attempted solutions; staff credentialing, and monitoring of technical and clinical processes with suitable modifications when standards are not met. But since the title of our research is quality control study of hemodialysis fluids that means we will only focus in our discussion on the three components of fluids used in the dialysis which are: acid concentrate, bicarbonate salt and processed water used. All the percent content of the sodium bicarbonate after the statistical analysis were in the range of $\pm 5\%$ from the standard value (Table I).

All results of water analysis tests were found in the range, except an increase in the hardness of Ebnauf hospital water, and this may cause damage in the artificial kidney (Table II).

TABLE I. Sodium bicarbonate assay.

| Sample | Mean Endpoint (ml) | Standard Deviation S.D. | Relative Standard Deviation R.S.D. | Coefficient of Variation C.V. | Percent content % |
|-----------|-----------------------|----------------------------|---------------------------------------|----------------------------------|----------------------|
| Gambro | 18.2 | 0.3606 | 0.0198 | 1.978 | 96.83 |
| China | 18.7 | 0.5770 | 0.0320 | 3.200 | 96.65 |
| Fresenius | 19.7 | 0.5300 | 0.0270 | 2.700 | 104.80 |

TABLE II. Results of water analysis.

| Test | Water Stated for Dialysis (Standard value) | Police Hospital | Soba University Hospital | Khartoum Hospital | AlShaheeda Salma Center | Children Hospital Ibnauf |
|------------------------------|---|--------------------|-----------------------------|----------------------|----------------------------|-----------------------------|
| PH | 6.50--7.50 | 6.70 | 7.39 | 7.50 | 8.48 | 6.80 |
| Specific Gravity of Water | 1.0000 gm/ml | 0.9995 | 0.9712 | 1.0002 | 1.0000 | 1.0011 |
| Water Hardness | <0.2000 mmol/L | 0.2400 | 0.0872 | 0.1223 | 0.0641 | 1.2620 |

The pyrogen free test of the processed water should isolate no bacteria, turbidity measurement should be non-destructive and the direct microscopic count should be insignificant. The pyrogen free test (present absent test) revealed presence of spore forming bacteria in both of Alshaheeda salma and Khartoum hospital (Table III).

The presence of this kind of bacteria is extremely dangerous and may be lethal, since bacteria in water of hemodialysis can cause septicemia, septicemia is a serious life-threatening infection that get worse very quickly. As we witnessed the water processing room in Khartoum hospital

was dirty, wet, and many damaged devices scattered here and there, we observed there is no interest of how the process is going on, the same situation was in ibnauf hospital, but Alshaheedaslma center and police are more better.

Analysis of elements in the concentrated acid, all elements were in the range of $\pm 5\%$ of the standard value, with exception of potassium, with minor differences between hospitals, but yet these differences are not with known danger, and this may be due to differences in the storage conditions, and they considered insignificant (Table IV).

TABLE III. The pyrogen free test.

| Test* | Police Hospital | Soba University Hospital | Khartoum Hospital | AlShaheeda Salma Center | Children's Hospital Ibauf |
|--------------------------|-----------------|--------------------------|--|--|---------------------------|
| Direct microscopic count | Not significant | Not significant | Not significant | Not significant | Not significant |
| Turbidity measurement | Non destructive | Non destructive | Fast | Fast | Non destructive |
| Bacteria isolated | No | No | Bacillus spore forming , bacteria isolated | Bacillus spore forming , bacteria isolated | No |

*These results out of three reading.

TABLE IV. The percentage of the four basic elements in the concentrated solution.

| Element | Standard Values ppm | Soba University Hospital (%) | Khartoum Hospital (%) | Alshaheedasalma Hospital (%) | Children's Hospital Ibauf (%) | Police Hospital (%) |
|-----------|---------------------|------------------------------|-----------------------|------------------------------|-------------------------------|---------------------|
| Calcium | 2448 | 99.5 | 103.2 | 100.8 | 103.0 | 103.2 |
| Potassium | 2733 | 113.0 | 106.9 | 108.0 | 105.6 | 108.8 |
| Magnesium | 420 | 95.0 | 96.3 | 95.4 | 95.5 | 97.5 |
| Sodium | 82831 | 99.8 | 103.5 | 98.6 | 97.6 | 97.3 |

Also the study was include across-sectional descriptive questionnaire, which was conducted among, 303 patients, from the total population of the study 62% were males. One hundred and eighty four from Khartoum, majority of the patients were between the age of 30 to 55 years. Most patients whom we have crossed through have not yet finished their educations or studied only up to the elementary level, and most women to the secondary. As they stopped for being married, this plus the decreased percentage of academic patients may show that education may not stop the disease, but surely will have a role in stopping it's progress and well educated patients may pay more attention to the early signs of it and can manage it before it reaches its acute stages.

Forty four percent of the patients under research are marked as unemployed which is justified for many reasons, When we neglected the house wives and the children patients we notice many unemployed patients of the worker left their jobs which is an understandable issue due to the severity of their disease but that affect their finance state and decrease their life level, so in spite of that 67% lived in brick houses and only 26% lived in clay's, and 61% lived in their own house and about 35% lived in rent house which is refer to a middle class living level (Fig. 1), many became cargo on their families which also affect their psychical state, but The National Center for Kidney do a great job in making the dialysis for free and since its opening patients from different places has there session for free ,they had some problems but they overcome it, also almost 71% of patients has health insurance which do little decrease in their financial demands.

Only 22% of patients have report occurrences of the disease in their families and 73 % of them stated that, they first the ewrmember in their family infected, so its seems it is not spread as an inherited disease and if such it proves that it may be mainly in Sudan due to the environmental conditions and the individual response to it. In spite of all problems and the challenges patients faced 87% of them stated that they have improved and 89 % never experience any complications which is an encouragement percent but need to be improved because our goal is 100 % improvement and free from complications also we should spot light on the excellent teams work in the hospitals which 92% have thank it powerfully but almost 18% has complain from the community attitude with

them yet with explanation we understand that most of them eliminate themselves first and many can't stand others sympathy and compassion.

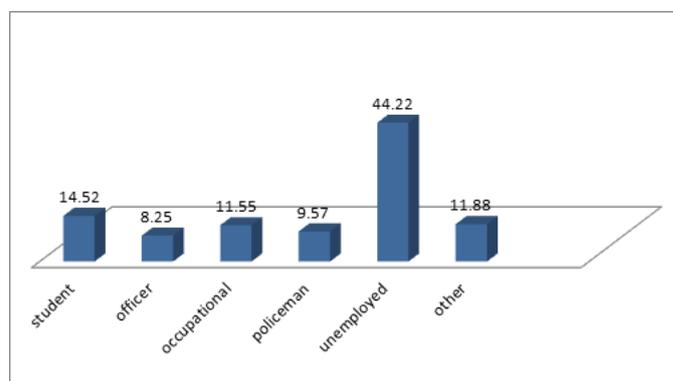


Fig. 1. Distribution of patients samples according to their jobs.

In Sudan most of the community empathize with patients and especially whose need frequent care as those go under dialysis , in our study we question the patients about what they feel about the community behavior with them and the answers were more and refine interaction with the community is needed.

In our study we noticed the increase percentage of patients who didn't know the cause of their kidney disease which is unacceptable for us but after researching we found out that many had been discovered at the end stage so a laboratory examinations will do no good because the kidneys fibrosis terminate any chance to know the cause, also many doctors referred this to many auto immune diseases but has no specialized laboratories for such tests here in Sudan.

In the 5 centers from where this questionnaire has been collected from the main cause that has risen above the others was the hypertensive nephrosclerolosis which is justified as we considered as a black color people and as studies through years proved that we have the untreatable kind of HTN, yet it is not the only reason there is also the poor management of the disease and the lack in the awareness of its danger and the late discovering of its presence after it done its damage to the kidneys and many has stated that they start dialysis after a short time of discovering there HTN (Fig. 2).

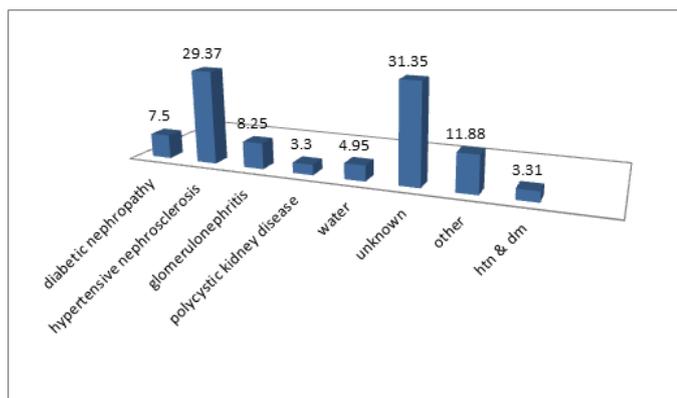


Fig. 2. Causes of chronic kidney disease.

The Dialysis Access

It is better to use fistula because it is on the hand and it doesn't cause infection unless it is not sterile but some patient suffer from disease prevent them from fistula. In spite of the wide spread of the disease in Sudan, Sudanese people still has lack in the interest and knowledge of the early signs of the disease and most of them came to the emergency with end stage kidney disease that require an immediate dialysis, 44% those cause a problem because they didn't give time to the centers to prepare a chair, fistula and other preparation needed for the dialysis which give a chance for many complications to appear also 23% start dialysis within a year of complaining and 24% within less than 5 years.

People needs to know the earlier signs of the disease and since it has signs that assemble the daily exhaustion it considered as a silent disease that you need to watch it carefully and keep eyes on its fragile signs.

Nearly half of the patients under dialysis 46% try to take other treatments and 37% of them use the Arabic gum and 16% try herbs while 31% try both of them but the problem is they didn't know that may be their usage for these treatments without consulting their doctors worsen their conditions or not.

A study aimed at assessing the effect of Gum Arabic oral treatment on the metabolic profile of chronic renal failure (CRF) patients was made at January 2008 in Faculty of Medicine, Department of Biochemistry and Nutrition, University of Gezira, Wad Medani, Sudan and they concluded that oral administration of Gum Arabic could conceivably alleviate adverse effects of chronic renal failure but for those who didn't start dialysis, with dialysis most of patients used it claimed that it didn't do any good and many said it made it worse so from what we've observed it's beneficial to use gum Arabic in the beginning of the disease due to its powerful effect in the alleviations of symptoms associated but once they starting the dialysis they have to stop taking it immediately.

From our study 18.2% of patients are infected with hepatitis B and C, hepatitis C is known as not an infectious disease so no need for separated rooms but with hepatitis B which can be transferred by the food, drinks and air. The major problem we witnessed in many hospitals is they do not

separate them in other section as should be which is a problem need to be solved.

IV. CONCLUSION

In view of our evaluation of the technical analysis and the survey that we have conducted in 5 dialysis centers in Khartoum state, we finally concluded that the acute chronic kidney disease is widely spread disease without any sign of control in the horizon. It appears that there is lack of recognizing the symptoms of the disease especially in its early stage cross the majority of the patients. The failure to recognize the disease in its early stage on the long term complicates the treatment and the chances for recovery and unfortunately forces the replacement therapy with all its complications.

That all because of the effect of many complicated factors, but what we think it's the most is the public lack of awareness about the signs of the disease and the shortage in the specialized laboratory with needed technique and centers that could ingestion the increased percentage of patients, and since the disease has five stages it's not possible patients didn't recognize one of them, and that lead to what most of patients states that they had no early signs and the cause of the disease is unknown, add to that the obvious lake of patient concern about the need to review a consultant when abnormal repeated signs appear and that also could be the cause of the relatively high percentage of children under dialysis.

In the analysis of the hemodialysis fluids and with the results we have had we conclude that the storage conditions need a very careful review and water processing rooms need to be changed and to take care of much more in many hospitals in all aspects, the processing technique, the cleanliness and the hygiene of the rooms.

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REFERENCES

- [1] G. R. Nimmo, S. M. Stewart, and P. J. English, "Myoglobin uric acute renal failure associated with major urological surgery- An avoidable problem?," *Intensive Care Med.*, vol. 14, no. 3, pp. 244-245, 1988.
- [2] J. W. Funder, P. T. Pearce, R. E. Smith, and A. I. Smith, "Mineralocorticoid action: target tissue specificity is enzyme, not receptor, mediated," *Science*, vol. 242, no. 4878, pp. 583-585, 1988.
- [3] J. Westendorf, *Anthranoic derivatives in adverse effects of herbal drugs*, Germany, springer-veerlag, 11, pp. 105-108, 1993.
- [4] B. A. Mueller, M. K. Scott, K. M. Sowinski, and K. A. Prag, "Noni juice (*Morinda citrifolia*) Hidden Potential for hyperkalemia?," *Am. J. Kidney Disease*, vol. 35, no. 2, pp. 310-312, 2000.
- [5] C. L. Chen, H. C. Fan, K. J. Chou, J. S. Wang, and H. M. Chung, "Acute nephropathy after ingestion of star fruit," *Am. J. Kidney Disease*, vol. 37, pp. 418-422, 2001.
- [6] A. Leung and S. Foster, *Anti-acne composition containing a poria cocos extract*, *Encyclopedia of common ingredients used in foods, and cosmetics*, American Botanical Council, John Wiley New York, 35: 71, 1995.



- [7] G. C. Alexander and A. R. Sehgal "Barriers to cadaveric renal transplantation among blacks, women, and the poor," *Journal of the American Medical Association*, vol. 280, no. 13, pp. 1148–1152, 1998.
- [8] A. J. Collins, J. Z. Ma, and S. E. Everson "Dialysis unit and patient characteristics associated with reuse practices and mortality: 1989–1993," *Journal of the American Society of Nephrology*, vol. 9, no. 11, pp. 2108–2117, 1998.
- [9] D. L. Frankenfield, J. R. Sugarman, R. J. Presley, et al. "Impact of facility size and profit status on intermediate outcomes in chronic dialysis patients," *American Journal of Kidney Diseases*, vol. 36, no. 2, pp. 318–326, 2000.
- [10] L. Freund, S. Burrows-Hudson, and P. Preisig, "Development of a patient classification system for chronic hemodialysis patients," *American Journal of Kidney Diseases*, vol. 31, no. 5, pp. 818–829, 1998.
- [11] P. P. Garg, K. D. Frick, M. Diener-West, et al. "Effect of the ownership of dialysis facilities on patients' survival and referral for transplantation," *New England Journal of Medicine*, vol. 341, no. 22, p. 1653–1660, 1999.
- [12] R. A. Irvin "Quality of care differences by ownership in United States renal dialysis facilities," *Journal of the American Society for Artificial Internal Organs*, vol. 46, no. 6, pp. 775–778, 2000.
- [13] S. Sankarasubbaiyan and J. L. Holley "An analysis of the increased demands placed on dialysis health care team members by functionally dependent hemodialysis patients," *American Journal of Kidney Diseases*, vol. 35, no. 6, pp. 1061–1067, 2000.