MaHTAS
Malaysian Health Technology Assessment Section

Single use dialyser versus reuse dialyser

Executive Summary

[Adapted from the report by DR JUNAINAH SABIRIN]

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Background

Renal replacement therapy in Malaysia has shown exponential growth since 1990. According to the 18th Report of The Malaysian Dialysis and Transplant Registry 2010, the number of dialysis patients in Malaysia has tripled in 10 years from 7,837 in 2001 to 21,245 in 2009. The number of haemodialysis centres for the whole of Malaysia increased from 208 in 2001 to 581 in 2010.In Malaysia, in 2010, 90% of patients undergoing haemodialysis were using reuse dialysers and 19% of patients used their dialysers for at least 13 times. About 80% of patients were using dialysers made from synthetic membrane. Dialyser reuse has historically been practised in light of perceived potential benefits for the dialysis provider and the patient. However, some of the original reasons are no longer valid. The availability of cheaper high-flux dialysers for single use means that the traditional benefit of the ability to reuse such dialysers no longer holds true. Potential errors and breakdowns in the reuse process are continuing concerns. The risk may move beyond bacteria into the realm of viruses and prions. In Ministry of Health (MOH) haemodialysis units, due to shortage of staffs, the dialyser reprocessing procedures are now performed by medical attendants. They are technically at risk of exposure to blood borne infections if adherence to standard precautions is not observed. It has been claimed that single use dialyser decreases rates of infection and contamination, likelihood errors and accidents, and risks associated with exposure to germicides and denatured blood products. Single use simplifies some of the operational aspects of haemodialysis and is convenient. The risk for medicolegal liability is also negligible in single use dialyser compared with reuse dialyser. Therefore, there is a need to reassess the dialyser reprocessing practice in MOH haemodialysis units.

Technical Features

Haemodialysis is a method of removing waste products such as creatinine and urea, as well as free water from blood when the kidneys are in renal failure. The haemodialysis machine pumps the patient's blood and the dialysate through the dialyser. The dialyser is the piece of equipment that actually filters the blood. The dialyser may either be discarded after each treatment or be reused. There are two ways of reusing dialysers: manual reuse, and automated reuse by means of a medical device. A majority of facilities that reprocess dialysers are now using a peracetic acid mixture as the primary reuse reagent. The other reuse reagents include formaldehyde, glutaraldehyde and sodium hypochlorite. Dialyser membranes come with different pore sizes. Those with smaller pore size are called "low-flux" and those with larger pore sizes are called "high-flux". Dialyser membranes are made of modified cellulose or synthetic material.

Policy Question

In MOH haemodialysis units, should single use dialyser be used for all haemodialysis patients or only for those with infectious diseases such as Hepatitis B, Hepatitis C, Hepatitis B & C co-infection or HIV infection?

Objectives

1. To assess the safety, effectiveness, economic implications, organizational, legal or environmental impacts of single use dialyser compared with reuse dialyser for haemodialysis of patients with end stage renal disease (ESRD) through a systematic review of the literature.(Part A)

2. To assess the cost-effectiveness of single use dialyser compared with reuse dialyser for haemodialysis of patients with ESRD in Malaysian public hospitals by conducting local economic evaluation.(Part B)

Methods

Part A (Systematic review of literature)

Studies were identified by searching electronic databases. The following databases were searched through the Ovid interface: MEDLINE(R) In-process and other Non-Indexed Citations and Ovid MEDLINE(R), EBM Reviews-Cochrane Database of Systematic Reviews, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews–Database of Abstracts of Review of Effects, EBM Reviews-Health Technology Assessment, EBM Reviews-NHS Economic Evaluation Database, EMBASE 1988 to 2013 Week 09. Parallel searches were run in PubMed. No limits were applied to the search. The last search was run on 14 February 2013. Additional articles were identified from reviewing the references of retrieved articles. General search engine was used to get additional web-based information. Studies were selected based on inclusion and exclusion criteria. All relevant literature was appraised using the Critical Appraisal Skills Programme (CASP) tool. All full text articles were graded based on guidelines from the U.S./Canadian Preventive Services Task Force.

Part B (Local economic evaluation)

The economic evaluation was designed from the provider (Ministry of Health) perspective based on haemodialysis unit in general public hospital. The evaluation was conducted using Markov cohort analysis where the average five years' costs and consequences (quality adjusted life years, QALY) for the patient who received either type of dialyzer were evaluated. The model structure was simplified from a published Canadian model whereby patient who received single use/reuse dialyzer progress to either requiring transplant, or remaining in the dialysis state, or died within 1 year cycle. The cost and benefit was discounted at 3%.

Result and conclusion

Part A (Systematic review of literature)

A total of 180 abstracts were screened using the inclusion and exclusion criteria. After reading, appraising and applying the inclusion and exclusion criteria to 87 full text articles, 30 full text articles comprising one systematic review, two RCTs, three cross over design, five cohort studies, one pre and post-intervention study, 11 cross sectional studies, three case series, one cost-utility analysis, two cost analysis and one cost minimisation analysis, were finally included for this review.

Safety of single use dialyser versus reuse dialyser

- There was fair level of evidence to suggest that:
  - Inadequate dialyser reuse practices were associated with outbreaks of bacterial infection and pyrogenic reactions.
  - Patients who reused dialysers were found to have 28% higher risk of septicaemia than patients who did not reuse dialysers and had a ninefold greater risk of death from septicaemia.
  - Reuse of dialyser was not associated with increased risk of HBV and HCV infection in either patients or staffs. However, (i) failure to identify and isolate HBV-infected patients during haemodialysis, (ii) sharing of staff, equipment, and supplies among patients, and (iii) failure to vaccinate susceptible patient were associated with outbreaks of HBV infection.
  - The incidence of new dialyser syndrome (first-use syndrome) has declined and was associated with regenerated cellulose and cuprophan membranes.
  - Reuse of hollow-fibre dialysers may be associated with anaphylactoid reactions.

- The evidence on intradialytic symptoms was inconclusive.

- The cumulative and long-term effects of chronic, low-dose exposure to reuse reagents (formaldehyde, hydrogen peroxide, sodium hypochlorite, glutaraldehyde and peracetic acid) cannot be determined.

Changes in membrane integrity

- There was fair to good level of evidence to suggest that small molecular weight solutes (urea, creatinine and phosphate) clearance were slightly greater for high- flux dialysers than low-flux dialysers. There was a trend for urea, creatinine and phosphate clearance to decrease with reuse for both high-flux and low-flux dialysers but these differences were not statistically significant.

- There was limited fair level of evidence to suggest that there was a small decline in dialysis dose (0.05 Kt/V units) when the mean frequency reuse was 3.8 to 13.8 times.

- There was fair to good level of evidence to suggest that clearance of large molecular weight solutes [β_2 Microglobulin (β_2M), retinol-binding protein (RBP)] was affected by reuse practices. β_2M clearance was low and not altered appreciably by reuse of low-flux dialysers. Clearance of β_2M was high for high-flux dialysers. However, clearance of β_2M and RBP for high-flux dialysers decreased with reuse. When bleach was included in germicide-based reprocessing cycles, β_2M clearances tend to increase. Eventhough the dialysers total cell volume (TCV) remained greater than 80%, reuse of high-flux dialysers does not ensure the maintenance of large solute clearance.

Clinical Effectiveness

- There was good level of evidence to suggest that there were no statistically significant differences in mortality between dialyser single use and dialyser reuse.

- There was fair level of evidence to suggest that reuse of dialysers was associated with higher hospitalisation rates from any cause. The higher rate of hospitalisation was observed with dialyser reuse using peracetic acid /acetic acid or formaldehyde.

Economic evaluation

- A cost-utility analysis performed in Canada in 2002 reported the cost saving that could be expected by switching from single use dialysis to heated citric acid reuse were small ranging from CAN $ 0 to CAN $ 739 per patient per year.

Organizational

- Reprocessing process entails multiple steps. Hence, personnel shall possess adequate education, training, or experience to understand and perform procedures outlined by the individual dialysis facilities.

- There was evidence to suggest that separation practices and ban on reuse of dialyser lower the incidence of Hepatitis B Virus or Hepatitis C Virus infection among patients.

Legal implication

- The requirement for reuse of dialyser in private healthcare facilities is included in the Malaysian Private Healthcare Facilities and Services Act 1998, Part XXII: Special requirements for haemodialysis facilities and services.

Environmental

- The dialysis procedure creates a considerable amount of waste (by single use or reuse practices). Hence, waste management needs to be part of dialysis provider system.

Part B (Local economic evaluation)

Single use was found to be more expensive but more effective than reuse. However, the incremental cost-effectiveness ratio (ICER) was found to be above the threshold of cost-effectiveness (MYR 4983655). The threshold of MYR 32,000 was used to determine the cost-effectiveness of the intervention at baseline. However, World Health Organization considered between one and three times gross domestic product (GDP) per capita as cost-effective. Threshold analysis showed that the breakeven point where both single use dialyser and reuse dialyser expected value are equal is MYR 1,418. Below this cost, the single use dialyser strategy would be favoured. It should be noted that the model has ignore possible effect of infectious disease contamination and associated building cost to accommodate high risk infected dialyser. Reuse seemed to be more cost-effective than single use dialyser.

Recommendation

Single use dialyser should be used for those with infectious diseases such as Hepatitis B, Hepatitis C, Hepatitis B & C co-infection or HIV infection, subjected to the availability of resource. Further economic evaluation using more complex model is advocated to determine the cost-effectiveness of using single use for all dialysed patients.

In line with the Ministry of Health guidance on Haemodialysis Quality and Standards and the Report of the Malaysian Dialysis & Transplant Registry where manual dialyser reprocessing system reported significantly higher risk for HCV seroconversion. Hence, automated reprocessing system for reuse of dialyser is advocated