REVIEW ARTICLE

Dialyzer Reuse: Justified Cost Saving for South Asian Region

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ABSTRACT

In spite of controversies, dialyzer reuse has remained an integral part of hemodialysis because of lower cost, good overall safety record, and improved membrane biocompatibility. Reuse declined in developed countries from the beginning of this century because of mass production of hemodialyzers at favourable price with better biocompatible membrane. Abandoning dialyzer reuse became challenging in South Asian region, where more than 40% of the population live below the International Poverty Line of $1.25 per day, less than 10% of end stage renal disease patients receive renal replacement therapy, and upto 70% of those starting dialysis stop treatment due to cost within the first 3 months. Dialyzer reuse is an efficient cost-saving method that allows the use of more efficient and expensive biocompatible synthetic membranes, thereby providing high-quality dialysis to individuals living in countries with limited medical resources without compromising the safety or effectiveness of the treatment.

Key Words: *Hemodialysis. Dialyzer reuse. Cost-saving. South Asia.*

INTRODUCTION

Reuse in medical practice: Reuse of medical device became common practice in healthcare as a result of being financially attractive.[1] Many medical devices are manufactured for repeated sterilization and reuse. Abandoning dialyzer reuse became challenging in South Asian region, where more than 40% of the population live below the International Poverty Line of $1.25 per day,[2] less than 10% of end stage renal disease patients receive renal replacement therapy, and upto 70% of those starting dialysis stop treatment due to cost within the first 3 months.[3] However, advances in synthetic-materials technology (introduction of new plastics) in the 1970s and 1980s led to an increase in the number of medical devices produced, labeled, and marketed as "for single-use only".[4]

The use of single-use medical devices helped to ensure device function and sterility, but it became especially difficult when the disposable item was very expensive, an example is an ultrasound catheter worth $5000.[5] Therefore, many healthcare institutions in the world started reusing these "single-use" medical devices primarily for economic reasons.[6]

Reusing medical devices for invasive procedures posed a potential risk of becoming contaminated or damaged and the resulting adverse events could offset the economic benefits.[4] Abandoning reuse because of these potential risks would imply that in most developing countries certain medical procedures, such as cardiac catheterization and angioplasty[7] will be conducted rarely because of the exorbitant cost.

Rather than abandoning reuse, most hospitals would prevent risks of contamination and damage to the reused medical device by adopting standardized, quality-controlled reprocessing procedures, thus minimizing reuse-related complications while retaining the economic benefits of reprocessing.[8]

Legal and ethical issues of reuse in medical practice: Ascertaining the legal responsibility and hence liability, if a patient is harmed by using reprocessed devices is the most important legal issue.[9] This responsibility and liability could be of the original manufacturer of the device, the re-processer of the device, the healthcare institution where a patient receives care or the care provider who treats the patient. In South Asia, there is an absences of clear regulations and legal precedents; thus, ethical principles must guide decisions for ensuring safe healthcare environment, protecting patients from undue harm, and informing about risks and benefits.

The ethics of reusing medical devices is complicated,[10] raising many ethical issues when a hospital decides to adopt a reuse policy.

Foremost ethical issue relates to the amount and details of information for consent regarding reuse of device. Should patients be informed even if the hospital has policies in place to ensure reprocessed items are as safe and effective as new devices and informing the patient could lead to unwarranted anxiety? Conversely reusing a device without consent could be viewed as hidden rationing, and seen as not respecting the autonomy of the patient.[11] Further, if new evidence reveals harms associated with reprocessed devices, do healthcare facilities and providers have a duty to trace affected patients and notify them of risks?

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Another ethical element of reusing single-use devices pertains to the responsibility of health institutions to be fiscally responsible. It seems unethical to use an item just once if it can be safely used again, as single use leads to additional burden on the payer of these devices or to reallocating money from other areas of healthcare. Advocates for reuse claim that hospitals can save as much as 50% by reprocessing single-use devices instead of buying new ones. However, financial gains may disappear if hospitals are dragged into costly lawsuits if patients suffer harm after being treated with reprocessed devices against manufacturer's instructions who strongly advocate single-uses (as their profits increase if hospitals replace rather than reuse their products).

Another ethical consideration is environmental stewardship. According to one study on reprocessing in USA, health sector contributes to the landfills about two billion kilograms of medical waste annually[12] and is second only to the food industry. Reprocessing is one strategy to decrease this waste.

There is a need to balance regulatory and legal responsibilities with the economic benefits associated with reusing these products bearing in mind ethical issues.

Commencement of reuse of dialyzer: The first description of hemodialyzer reuse appeared in 1964. Since that time, reuse of dialyzer has increased steadily and became an integral part of hemodialysis both in the developed and developing countries.[13,14] In 1997, reuse was practiced in 82% of the centers in the United States and a dialyzer was reused around 17 times.[15]

More reuse is done in larger facilities as compared to smaller ones and is highest in self-supporting and not-for-profit facilities mainly for economic reasons.

Automated reprocessing has increased over time, being preferred over manual reprocessing. In the United States, over 60% of centers practicing reuse use automated methods.[16] Quality improvement programs for dialysis have increased the frequency of automated repossessing over manual repossessing even in other countries.

Good quality control of the reprocessing procedures,[13,15,17,18] as a result of monitoring and standardization along with increased cost of newer synthetic membranes and reduced reimbursements (in USA),[19,20] has steadily increased the dialyzer reuse. Thereby allowing provision of higher dialysis doses in resource limited countries.[21] Bangladesh, a developing country, adopted dialyzer reuse actively with a total cost savings of 32%.[14] Dialyzer reuse is also being practiced in Nepal, where they found it cost effective as well as safe.[22]

Concerns with reusing dialyzer: Although the practice of reuse has been an integral part of dialysis since its inception, controversy has surrounded this practice till today.[23-25]

Mortality is the main concern while comparing single use versus reuse dialyzers. Occasional reports in mid 90s, have suggested higher mortality and morbidity with dialyzer reuse.[23,24] However, a number of studies in last 2 decade have found no significant differences in mortality, survival advantage or first hospitalization risk among patients treated with single-use dialyzers compared with dialyzers cleansed by using different reprocessing techniques.[26,27]

While considering toxicity from disinfectants, studies suggest that neither reuse nor the choice of sterilant appear to affect mortality.[23,28,29] Several pyrogenic reactions have been reported in reuse facilities utilizing formaldehyde,[15,30] but in each case, the outbreaks were attributed to the use of water supplies or dialysates that were contaminated and did not meet the AAMI (Association for the Advancement of Medical Instrumentation) standards. Now most reprocessing unit has been using renalin as sterilant rather than formaldehyde. Increased rates of infection have also been among the major concerns in the practice of dialyzer reuse. Increase rate of gram-negative bacterial infections have been reported which are attributed to inadequate exposure of the dialyzer to sterilant, failure of a technician to change gloves after working with a patient with a known arteriovenous fistula infection or due to the use of a water supply that did not meet AAMI standards rather than dialyzer reuse itself.[25,30,31] However, there is no increase in hepatitis C infection in practicing dialyzer reuse.[32,33]

Concerns about reduce delivered dose of dialysis and impaired removal of large molecules are also controversial.[34] Oxidative stress, a causative factor in atherogenesis and premature cardiovascular disease with reuse dialysis was less when compared to single use dialysis, but the difference was not statistically significant.[35]

Notwithstanding this controversies, the cost of single-use biocompatible dialyzers is still considerable, and most investigators continue to maintain that the practice of reuse is safe,[36,37] provided it is performed according to recognized reuse protocols, including the dialyzer manufacturer's instructions.

Reason for shifting back to single use: Initially reprocessing and reusing of dialyzers was done to improve blood-membrane biocompatibility and prevent first-use syndromes. However, in the late 1980s and early 1990s, availability of more biocompatible synthetic membranes made the problem of "first use" syndrome irrelevant, and the need to save cost became the main reason for the continued practice of dialyzer reuse.[38] In the beginning of this century, there was mass production of economically priced dialyzer in the United States by

Fresenius Medical Care-North America which offset the cost benefit of dialyzer reuse. This sharply decreased the prevalence of reuse and in 2005 only 40% of dialysis units in the United States were reusing dialyzers,[39] and this trend was similar in 2012.[40]

Situation in South Asia region: South Asia is the most populous and densely populated geographical region in the world. It is home to 16.5% of the world and about 34% of Asia's population.[41]

South Asia is the poorest region on the earth after Sub-Saharan Africa. According to the poverty data of World Bank, more than 40% of the population in the region lives below the International Poverty Line of $1.25 per day in 2005.[2] The recent data released by the World Bank's Development Research Group show that 22% of the developing world's population - or 1.29 billion people - lived on $1.25 or less a day in 2008 slightly better than that in 2005.There was only a small drop in the number of people living on less than $2 per day, from 2.59 billion in 1981 to 2.47 billion in 2008.[42] According to the World Bank, 70% of the South Asian population and about 75% of South Asia's poor live in rural areas.[43]

ESRD is an overwhelming economic, health and public health problem in this region. Lack of national registries and surveys make estimation of the burden of ESRD difficult in South Asia. However, a population based study assessed the age adjusted incidence at 232 cases per million populations per year in India[44,45] while the incidence of ESRD is estimated to be 100/million population in Pakistan.[46] If these figures are similar in other parts of this region, it would indicate that 250,000-300,000 new patients need RRT every year in South Asia. Despite a heavy burden of ESRD in this region, relatively few patients receive RRT, less than 10% of Indian ESRD patients receive RRT[47] while upto 70% of those starting dialysis stop treatment, due to cost, within the first 3 months.[3] ESRD treatment facilities are available only in main cities, requiring most patients to travel long distances to seek care. Many patients unfortunately, never come to medical attention.

While high cost and possibly nephrologists' bias have limited the growth of peritoneal dialysis in this region, economic issues and lack of an effective deceased donor programs has limited the availability of transplant and, therefore, hemodialysis is the most prevalent form of RRT in this region. In contrast to rest of the world, where the emphasis is on improving the quality of life and long-term survival through effective hemodialysis, the enormous cost of therapy limit the continuation of treatment in this region.[48] It is common for patients to reduce the dialysis frequency as financial resources dwindle-leading ultimately to discontinuation of dialysis and death.

The exact cost of RRT is difficult to estimate,[49] it varies with the prescription and the way a unit is set up, estimated annual hemodialysis costs per patient is approximately US$ 5000 in India.[3] This includes transportation costs, and loss of earning for both patient and attendants.[46] The overall treatment cost, although less in dollar terms than that in the developed countries (because of lower staff salaries and low cost of medicines) but it still remains out of reach for most of the population. It is, therefore, not surprising that maintenance hemodialysis is rarely the Government priority (as per capita expenditure on health is extremely low and the cost of hemodialysis is extremely high), and hemodialysis is often confined to the private sector. Unlike the developed world, the concept of health insurance (both government funded and private) is at a primitive stage in this region, consequently most patients have to pay out of their own pocket or are supported by charity, thereby imposing an enormous financial burden on patients, their families and charitable organizations.

The mean age of patients requiring RRT in South Asian countries is much lower (46 ± 12) as compared to the rest of the world.[44,50] This implies that the ESRD population in these countries is made up of individuals in the most productive years of their lives, who often are the sole wage earners of families with multiple dependents.

Is dialyzer reuse justified in South Asia? In theory, limited benefits could be sacrificed for substantial resource savings, permitting reallocation to higher-value alternatives, like forgoing newer, expensive but more effective technologies in favour of older and cheaper, slightly less effective options. Innovations, which capitalize on favourable cost-quality tradeoffs, are omnipresent in other markets and are especially attractive in a weak economy. Automobile manufacturers produce vehicles that lack certain safety features like side airbags because some consumers are willing to forgo these options to reduce the purchase price. However, these cost-effective innovations or tactics are exceedingly rare in medicine markets especially in the Western world.[51] Several reasons may explain this medical exceptionalism.[52]

First, the “price insensitivity” of healthcare may blunt any impetus for decremented cost-effective innovations because incentives both for physicians to control costs and for patients to demand less expensive treatment are lacking, as insurance shields them from the direct costs of care which is not the case in South Asia region.

Second, the required savings per quality-adjusted life-years lost for decremented cost-effective care may be so high that many possible interventions may be unacceptable.

Finally, as medical decisions frequently have concrete and obvious risks for serious morbidity and mortality use of less effective and less expensive medical technologies may elicit ethical distaste on use of

affordable substandard therapies; this has stirred controversy even in the poorest settings.

Weak economy and the looming healthcare crisis in South Asia may create healthcare opportunities for cost-saving tactics, particularly if it involves more cost sharing or renders clinical decision making more price-sensitive. These cost-saving innovations or tactics may improve overall outcomes, even when they are slightly less effective options.

Reusing dialyzer with newer larger biocompatible synthetic membranes provides high-quality, effective and safe dialysis which is environmentally friendly with much needed economic benefit in the face of cost inflation and limited medical resources.

Marketing strategy by manufacturers may also be responsible for promoting single use and discouraging dialyzer reprocessing. The entire circumstances in South Asia is quite different from that of the western world, recommendations made for entirely different population, should be thoroughly reviewed before considering applying them in this part of the world. While certain western countries may be able to afford single use, this may not be feasible for South Asian countries as it is feared that higher prices for single use in these countries will be at the expense of dialysis patients and healthcare systems.[53]

Future outlook: Lack of standards for reprocessing dialyzer, breach in reusing protocol and lack of reprocessing policy are among the crucial factors working against the success of reuse. High priority should be given in developing and implementing specific guidelines and standards for reprocessing and reuse of dialyzers in South Asia. The ideal approach would be for the regulatory agencies, manufacturers, academic institutions, and healthcare institutions to work together to develop guidelines, suited best to this region, however, because of conflicts of interest this may not be easy. The recommendations may include the creation of a reuse committee, written reprocessing procedures for dialyzer reuse, validation of sterility and functionality of dialyzer and assurance of quality through monitoring, sampling, inspection and periodic review of external factors (such as changes in dialyzer design or materials/ membranes).

Infection control guidance for the reprocessing of dialyzers should stress the importance of pre-cleaning of gross debris, using appropriate sterilizing agents, maintaining water quality standards, conducting surveillance for adverse events, and training of healthcare personnel. Despite the lack of clinical studies, strict adherence to these precise basic infection control measures should substantially reduce potential adverse events due to dialyzer reuse.

Transferring the responsibility of reprocessing to a third party, such as a reprocessing company that may have standardized, quality-controlled reprocessing procedures may help in countering breach in reprocessing policy.

There is also an urgent need to explore ways of providing high quality, lower cost dialyzers. The high cost of imported consumables contributes the majority of expense of dialysis. Domestic manufacturing might significantly reduce these costs.[54] Given the scale of local demand, domestic manufacturing could be made economically feasible by exporting as well as selling to local markets. Governments may need to provide incentives to foreign companies to facilitate licensing and registration for dialysis items, or implement programs of cost containment in coordination with suppliers.[55]

Dialysis services need to be affordable, cost-effective and suited to local circumstances. This will only be achieved through educating patient, public and providers by developing an effective public policy, and through ongoing support from international professional bodies, government and non-government organizations.

Till specific guidelines of dialyzer reuse are available for resource-limited settings, one may follow the National Kidney Foundation, Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines for dialyzer reuse.[56] Reprocessing guidelines suggest adhering to the Association for the Advancement of Medical Instrumentation (AAMI) standards and recommended practices for reuse of hemodialyzers.[57] Reprocessed dialyzers should at least have 80% of the original measured blood compartment volume and 80% urea (or ionic) clearance of the original measured clearance. The use of poorly biocompatible, unmodified cellulose dialyzer membranes for HD is discouraged.

It is crucial that future research focus on the cost and environmental consequences of dialysis by comparing disinfectant-related waste with reuse, and solid waste with single use. Those involved in hemodialysis have a responsibility to explore ways to lessen environmental consequences of single-use as a standard practice.

CONCLUSION

Dialyzer reuse seems to be an effective cost saving approach, legitimized both by clinical use as well as studies in the literature, especially in the face of cost inflation and limited medical resources. Reuse allows the use of more efficient and expensive larger biocompatible synthetic membranes thereby providing high quality dialysis to patients. Lack of standards for reprocessing dialyzer in resource-limited settings, breach in protocols for reusing and lack of reprocessing policy are the key factors working against the success of reuse. Specific guidelines and standards are needed for reprocessing and reuse of dialyzers in South Asia so that the economic benefits of reprocessing are maintained and reuse-related liability decreases with no or limited compromise on safety and efficacy.

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