REVIEW ARTICLE

Reusing dialyzer in low income countries: A good cost saving tactic with complex ethics

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Abstract

Despite almost universal practice of dialyzer reuse from the earliest days of haemodialysis, reusing dialyzer always remains a controversial issue and several ethical concerns have been raised. Some of the important are safety of reuse over single use, informed consent of the patient, conflict of interest on the part of physician or manufacturer, fiscal responsibility and environmental stewardship. Indeed, at the beginning of this century, there was a drastic shift of practice in favour of single use in developed countries due to availability of biocompatible haemodialyzers, at favourable price. Despite this mega shift, dialyzer reuse is still widely practised in low-income countries. Considering cost inflation and limited medical resources in such countries, dialyzer reuse may be justified as a cost-saving strategy for this part of world. However, it poses the same ethical questions to us which were a matter of debate for the western world in the 1980s and 1990s. This review of literature was planned to revisit and highlight these concerns.

Keywords: Dialyzer reuse, Low-income countries, Cost saving, Ethics.

Introduction

Dialyzer reuse is an integral part of dialysis since its inception. In spite of its economic benefit,[1,2] good overall safety record[3-5] and improved membrane biocompatibility, reusing dialyzer remains a controversial issue[6-8] all over the world. Several ethical concerns were raised and discussed in detail during the 1980s and the 1990s in the western world,[9] like whether dialyzers reuse is as good as single use, or is there any need of informed consent, and is there a conflict of interest. Fiscal responsibility and environmental stewardship were also questioned. At the beginning of this century due to mass production of biocompatible haemodialyzers, available at a favourable price,[10] there was a rapid decline in reuse of dialyzer in the developed countries.[11] For instance, in the United States, reuse dialyzer was in practice in 82% cases in 1997[12] which declined to only 40% in 2005.[13]

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Despite this large shift to single-use dialyzer in developed countries, the practice of dialyzer reuse prevailed in low-income countries.[14] Hypothetically, limited benefits could be sacrificed for substantial resource savings, permitting reallocation to higher-value alternatives.[15] Based on this conjecture, dialyzer reuse was accepted in low-income countries.[16] The credence of this speculation didn't only provide a significant economic benefit, but also allowed the use of better dialyzers with ongoing cost inflation and limited medical resources. Therefore, dialyzer reuse may be justified as a cost-saving strategy in this part of the world.[17,18] However, accepting dialyzer reuse over single use raises the same ethical dilemma to us. This review of literature was planned to revisit and highlight these concerns.

Whether dialyzers reuse is as good as single use?

Reprocessing of dialyzers has traditionally been acknowledged to improve blood-membrane biocompatibility and prevent first-use syndromes along with considerable financial savings.

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 to 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 that are suited best to this region, but because of conflicts of interest, this may not be easy. Till specific guidelines of dialyzer reuse are available in resource-limited settings, one may follow the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines for dialyzer reuse.[19] Reprocessing guidelines suggest adhering to the Association for the Advancement of Medical Instrumentation (AAMI) Standards and Recommended Practices for reuse of haemodialyzers.[20] 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 haemodialysis (HD) is discouraged.

Further, widespread availability of biocompatible membrane offset is the claimed benefit of dialyzer reuse.[10,11] Therefore the bio-incompatible membranes were abandoned. On the other hand, single use of dialyzer no doubt helps to ensure dialyzer function and sterility but also prevents infection.

The issue of whether dialyzer reuse is still as good as single use, as claimed in past, has to be revisited by the medical community. There are other options like reuse of bio-incompatible membranes which will be very economical or to reuse biocompatible membranes which although not as cost-effective as the reuse of bio-incompatible membranes, but better than the single use.

What about informed consent?

Another issue involved is that of informed consent.[21,22] Informed consent is the traditional means by which the dignity and autonomy of the patient are protected against the interests, finances and otherwise of other persons or groups. If an institution or a government in low-income country accepts dialyzer reuse as justified alternative to single use in its circumstances, ethical norms or rules should not be overlooked to govern their use.

There is an argument that if a hospital or government has policies in place to ensure reprocessed items are as safe and effective as new devices, consent is not necessary because it may lead to an unwarranted worry.[23,24] Further, in the face of rapid advancement of technology, where the long-term effects are unknown, and where treatment modalities are complex (sometime beyond the capability of a patient to comprehend the details and intricacies of the procedures that they are consenting to), it will not be realistic to require informed consent to specific aspects of these modalities.[24]

On the other hand, reusing a dialyzer without consent could be viewed as "hidden rationing," and seen as not respecting the autonomy of the patient.[23] Patients should know the pros and cons associated with any procedure that may be used in their treatment so that they can decide what treatment they want to have.[22,25] The economic benefit of reusing dialyzer must be balanced against the patient's right to a safe healthcare environment. In such cases, the care providers may face liability for adopting practices that are designed for financial reasons rather than for patient's benefit.

As the dialysis therapy in most of the low-income countries is paid not by patients but by federal funds or welfare services,[16] dialysis patients have fewer options than other patients to articulate and defend their freedom, autonomy and dignity.[14] This vulnerable situation puts more responsibility on the shoulder of health providers to stand more firmly to the three basic moral principles i.e., respect for autonomy, beneficence, and justice.

Is there a conflict of interest?

Dialyzer reuse has been supported by many practitioners because of cost and therapeutic advantages. However, these therapeutic advantages are both minimal and disputed and the information provided with regarding the cost-benefit equation has been challenged.[10,26,27] The moral issue that physicians will have to face is to decide between the demands of their patients for the highest possible quality of care and society's demand that the costs of providing this care be lowered. The primary beneficiaries of widespread dialyzer reuse would be the general public in the form of decreased costs for the end-stage renal disease (ESRD) programme and the physicians who are involved in the provision of dialysis for profit as the practice of reuse reduces their costs.[25] Here, the question arises if the physician has a financial interest in the treatment which could be associated with a conflict of interest in the provision of care (i.e. trading more reuses with less expenditure for poorer patient outcomes).[21]

On the other hand, it should also be kept in mind that the manufacturers of dialyzers, of course, have an interest in dialyzer sales for single use, which has led to a marketing strategy promoting single use and disparaging dialyzer reprocessing.[28]

It's a tough call, but one must need to maintain the most efficient and economic care balance while maintaining patient health and safety.

Are we fiscally responsible?

Another ethical element of reusing dialyzers relate 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,[29] as single use leads to additional burden on the financier of these devices or one has to reallocate 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 instructions who strongly advocate single uses[30] (as their profits

increase if hospitals replace rather than reuse their products). This may be far more important from the moral point of view for physicians than the legal lawsuits in many low-income countries because of lack of awareness of patients about their rights. Further, if new evidence reveals harms associated with reprocessed dialyzer, will healthcare facilities and providers trace affected patients and notify them of risks and compensate for the fiscal loss (if any) related to this?

Do we commit to be steward of the environment as well?

Another ethical consideration is environmental stewardship.[23] Environmental stewardship refers to responsible use and protection of the natural environment through conservation and sustainable practices. If it's good for the planet, medical community should realise that just as we care for our patients and are committed to ensuring their well-being, we must care for the environment and commit to its well-being for future generations. According to one study on reprocessing in USA, the American healthcare sector is second only to the food industry in contributing to landfills, disposing of an estimated four billion pounds of medical waste annually.[31] Reprocessing is one strategy to decrease waste.[32] We must continually strive to be not only a provider of best patient care, but also an environmental leader in the healthcare industry. Decisions of practicing dialyzer reuse versus single use must be taken in the best interest of the patient while accepting and acknowledging responsibility for the environmental impact of our decision.[11]

Conclusion

In the absence of uniform decision about the practice of dialyzer reuse within the medical community, it seems difficult whether to stand for the theory of sacrifising limited benefit for substantial resource-savings and responsibility of health institutions to be fiscally responsible or to vote for respecting the autonomy of the patient. It is not easy to generate a uniform opinion in a scenario where physician may have a financial interest in promoting dialyzer reuse and manufacturers may have an interest in dialyzer sales for single use, and where medical community has to play its role as the provider of best patient care while maintaining its commitment for environmental care. The only conclusion we can come up with is that the dialyzers reuse may be a justified cost-saving tactic for low-income countries but there are complex unanswered ethical questions surrounding the debate.

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