SPECIAL COMMUNICATION

REPROCESSING CARDIAC ELECTROPHYSIOLOGY CATHETERS: RECOMMENDATIONS OF PAK HRS TASK FORCE AND REVIEW OF LITERATURE

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Cardiac Electrophysiology Study (EPS) and Ablation procedures are definitive treatment for multiple common arrhythmias. The major component of the cost of the procedure is the expense of the catheters. Many centres around the world used to reuse these catheters but few years ago started noticing Single Use Device (SUD) labelling appearing on them without any change in the catheters.[1] This SUD labelling certifies that this can be safely used once but does not mean that it cannot be used again. Based on this the Federal Drug Authority of the United States shifted the liability of the reused device on the entity reprocessing it. Despite this, due to their high cost these catheters are reused not just in low income countries but also in many European and North American centres.[1-2] This reuse is supported by extensive literature showing safety in reusing these catheters.

Currently there are no specific regulatory guidelines either at the federal or provincial levels for reuse of electrophysiology catheters in Pakistan. The Pakistan Heart Rhythm Society created this task force to review the literature and give recommendations to guide both the Heart Rhythm physician community as well as provide basis for discussion with regulatory authorities. This task force includes members from major public and private institutions performing cardiac electrophysiology procedures. The members included specialists in cardiac electrophysiology, infectious diseases and certified infection control staff.

This literature review has been done to give recommendations for use of reprocessed electrophysiology catheters specifically for the patients in Pakistan. Since more than 90 percent of EP procedures in Pakistan are for supraventricular tachycardia (SVT) ablations, costs and other measures in this document are calculated using SVT ablation for modelling. Moreover, connecting cables and other equipment that are located outside the body but in the sterile field are not addressed in this document as they do not have significant safety impact. Similarly, catheters with lumens or balloons are not addressed in this document due to paucity of studies to demonstrate safety.

The following aspects of using SUD or reprocessed catheters were compared and reviewed before final recommendations of this committee at the end of this paper.

1. Cost
2. Safety
3. Unused expired catheters
4. International practices
5. Ethics
6. Hospital Policies and personnel
7. Cleaning and sterilization procedures.

Cost: The cost of catheters is the driving force behind the movement to reprocess catheters. In public sector hospitals where personnel and capital equipment costs are already fixed, EP catheters constitute roughly 98 percent of the cost of the procedure. Current costs for catheters used in a single EP procedure are as below based on available information in August 2021. These costs are based on the current USD –PKR parity.

Table 1: Cost of Catheters for one SVT ablation with Single Use Devices

Catheter	Number Used	Cost Average (range)	Total
Fixed Quadripolar	2	40,000 (30,000-50,000)	80,000
CS Catheter	1	60,000 (30,000-70,000)	60,000
Ablation Catheter	1.3*	100,000 (50,000-150,000)	150,000
Total			**290,000**

**A second ablation catheter with different curve has to be used in case of inadequate reach or difficulty manoeuvring approximately in 1 in 3 cases.*

The cost per procedure based on number of times a catheter is reprocessed is calculated as below in Table 2.

Table 2: Cost of Catheters for one SVT ablation using reprocessed catheters

Catheter	Number	Cost Average (range)	Times reused	Total
Fixed Quadripolar	2	40,000 (30,000-50,000)	10	8,000
CS Catheter	1	60,000 (30,000-70,000)	10	6,000
Ablation Catheter	1.3*	100,000 (50,000-230,000)	6	25,000
Total				**39,000**

**A second ablation catheter with different curve has to be used in case of inadequate reach or difficulty manoeuvring approximately in 1 in 3 cases.*

Based on current estimates as above the cost of a procedure using reprocessed catheters is approximately 12% of single use catheter procedure or savings of **PKR 251,000 per case**. This decreases the burden on the public sector hospitals where the bulk of these procedures are being done as well as on individual patients who are having the procedure at private hospitals.

Since all these catheters are imported this will reflect in significant savings in foreign exchange for the country as well.

Table 3: National savings in USD using reprocessed catheters

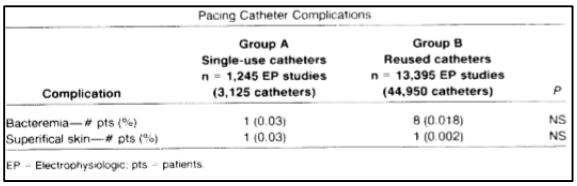
	Cost (PKR)	Cost (USD)*	Procedures / year	Total USD
Single Used Catheter	290,000	1,812	3,000	5,436,000
Reprocessed Catheter	39,000	243	3,000	731,250
Savings in USD per year				**4,704,000**

**USD_PKR exchange calculated at 160 PKR/USD*

Safety: Multiple studies have failed to demonstrate an increased risk of infection or other complications with catheter reuse compared to single use.

An early study with 48,075 catheters found no difference in infection rates between centres that had reused catheters compared to centres with single-use catheters.[3] (see Figure 1).

Another study done on ablation catheters (Marriam-Webster catheters) utilized a vigorous methodology to assess torque handling, deflection, infections and microscopic changes. They showed that catheters could be used multiple times before loss of function would require them to be discarded. No infections were reported. They noted on microscopic exam that there was loss of glue joining the distal ablation electrode to the shaft. The authors felt that this loss, which was measured in fractions of millimeters, was possibly due to high temperatures of up to 100 degrees centigrade that were achieved with the thermocouple ablation system available at the time. Current RF ablation practices where temperatures are kept between 55 to 65 degrees may not cause this insignificant issue. Moreover no adverse effects from this loss of glue were reported.[4]

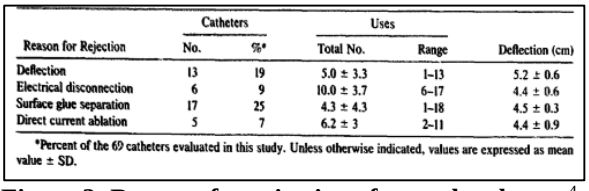


Pacing Catheter Complications

Complication	Group A Single-use catheters n = 1,245 EP studies (3,125 catheters)	Group B Reused catheters n = 13,395 EP studies (44,950 catheters)	P
Bacteremia—# pts (%)	1 (0.03)	8 (0.018)	NS
Superifical skin—# pts (%)	1 (0.03)	1 (0.002)	NS

EP = Electrophysiologic; pts = patients.

Figure 1: Comparison of infection in patients with Single-use and Reused catheters[3]



Reason for Rejection	Catheters No.	Catheters %*	Uses Total No.	Uses Range	Deflection (cm)
Deflection	13	19	5.0 ± 3.3	1–13	5.2 ± 0.6
Electrical disconnection	6	9	10.0 ± 3.7	6–17	4.4 ± 0.6
Surface glue separation	17	25	4.3 ± 4.3	1–18	4.5 ± 0.3
Direct current ablation	5	7	6.2 ± 3	2–11	4.4 ± 0.9

*Percent of the 69 catheters evaluated in this study. Unless otherwise indicated, values are expressed as mean value ± SD.

Figure 2: Reasons for rejection of reused catheters[4]

In another study the effectiveness of re-sterilization using Ethylene Oxide (ETO) was assessed by dipping various catheter components in a standardised broth of Bacillus subtillis (a spore forming bacteria) followed by ETO cycles of 2, 4 or 6 hours. No bacterial growth was noted in any of the groups when these catheter components were cultured.[5]

Similarly after use of ETO based cleaning protocol in catheters experimentally contaminated with duck hepatitis B virus (a surrogate for human hepatitis B virus), bovine viral diarrhea virus (a surrogate for human hepatitis C virus), and human coxsackie type B3 virus there was no evidence of any residual virus.[6]

However, it has been noted that ETO residue present on catheters in one of these studies was greater than permissible levels despite aeration of up to 48 hours.[5] Further studies showed that aeration for 2 weeks or using a special decontamination protocol of 14 hours brought the ETO level to within acceptable limits.[7]

Unused Expired Catheters: Expiry date for items reflects the time period during which the product is

expected to retain its qualities. Expired items are meant to be replaced and destroyed. Although no specific evidence could be found to advocate for or against use of expired EP catheters it should be noted that in special circumstances even FDA allows use of expired products provided, they are adequately evaluated. These special circumstances pertained to the US stock piled medicines and vaccines as destroying them would cause massive financial loss and access to new batches may take time.[8]

Unique circumstances in Pakistan result in these products remaining on shelves at time of expiry. Destroying these catheters is a very expensive option and many vendors do not agree to replace with longer duration expiry free of cost. Many of these catheters are ones that are rarely used but need to be on the shelf should they be needed during a case and hence expire without being used. As these are not frequently used items vendors don't stock them either and they are difficult to obtain often taking months to replace on request.

EP catheters are robust and made of materials that are short term non degradable if stored under appropriate conditions. They retain their shape and function up to several years after the expiry date (consensus of authors based on experience). There is concern however whether sterility would be maintained which can be addressed by resterilizing the catheters and labelling with new sterility expiry date.

International Practices: The United States Federal Drug Authority does not forbid reuse of catheters but entities that reprocess them have to register and be subject to regulation.[1] The North American Society of Pacing and Electrophysiology (now known as Heart Rhythm Society) Task Force on the subject states that reprocessing is a safe and cost effective measure if catheters are meticulously cleaned, sterilized, and inspected in accordance with accepted standards of practice as specified by FDA.[1]

A 2021 publication surveyed respondents from 34 European countries and found that around two thirds of the electrophysiologists had experience with resterilized equipment and the majority would be using reprocessed ablation and diagnostic catheters.[2] However there is no uniform regulation regarding reprocessing in EU. Spain, Italy, and France have banned this. Germany allows reprocessing if certain standards are met. It is also accepted in Belgium, Portugal, and Sweden.

From amongst the developing world an extensive review and recommendations by an experts writing committee of Cardiological Society of India proposed reuse of EP catheters and suggested protocols to ensure safety.[9]

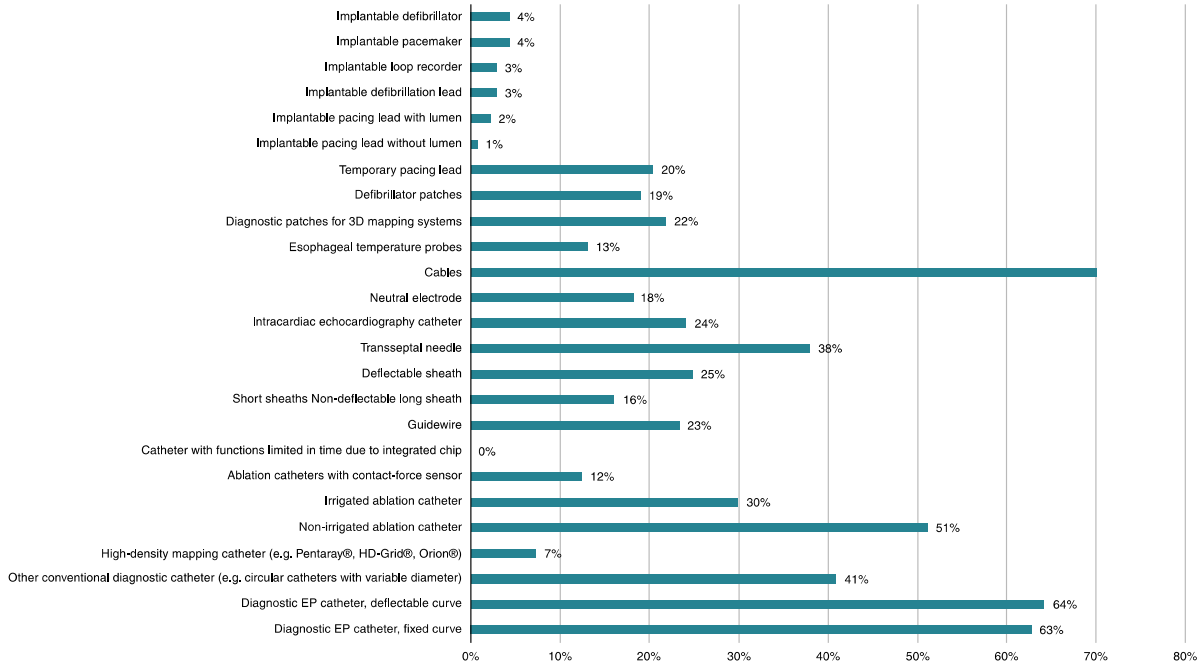


Figure 3: Percent of European electrophysiologists using reprocessed EP equipment[2]

Consent and Ethical Issues: From the ethical perspective at time of the consent prior to the procedure patients need to be told of all substantial risks. Since the risk of reprocessed catheters is not increased or so low that it has not been demonstrated then there may be no ethical reason to discuss it with the patients as per one group of ethicists. Discussing insignificant risks increases irrational fear and can prevent patients from receiving therapies they need. Patients should be informed if they ask about the hospital's policy, and they have the right to request that reprocessed catheters not be used.[1]

Since the principal reason for using these catheters is for reducing costs, these savings must be passed on to the payer whether it is a third party (patient employer or insurance company) or the patient themselves (self-pay). It would be unethical to use reprocessed catheters while billing for new catheters.

Infrastructure, Personnel and Institutional Policies: Prior to embarking on a re-sterilization process for SUD catheters the following systems need to be ensured in the institutions embarking on the process. Multiple excellent guidelines and recommendations are available and should be followed.[10-12] The following are some of the recommendations that should be in place in institutes reusing catheters

1. A functioning CSSD department with policies and procedures that meet standards needs to be in place in any institution contemplating reprocessing catheters.
2. A committee consisting of representatives from department of infection control, electrophysiology department, CSSD, and infectious disease should evaluate each category of items to assess if it truly needs to be reused or single use.
3. A robust system of Quality Control checks including documentation of compliance to SOPs.
4. A mechanism to trace each item that is reprocessed along with the number of times it has been reprocessed along with the patient it is used on.
5. System to report and record any adverse effects that may be attributed to reprocessing the catheters.

Cleaning and Sterilization Procedure: Based on literature review and current standard CSSD practices the following standard processes are recommended.

Inspection and Catheter assessment:

At the end of each procedure the electrophysiologist should examine all catheters that are candidates for reprocessing and ensure that

1. The signal quality from the catheter at the end of the procedure was satisfactory
2. There is no physical damage to the catheter surface or connector
3. Catheters with fixed curve have maintained their shape
4. Mechanism for variable curve catheters is intact and prescribed curve formed

Pre-sterilization Cleaning

1. Blood should be removed immediately by rinsing with distilled water.
2. Disassemble prior to cleaning.
3. Immerse equipment/device in enzymatic agent for 10 minutes.
4. Clean outer surface properly.
5. Rinse with minimum 50ml of Heparinized 0.9% Normal Saline (10 units/ml).
6. Rinse with enzymatic solution afterwards.
7. Rinse thoroughly with distilled water.
8. Equipment/devices should be dried by hand with a clean, lint-free towel.

Packing

1. The catheter should be packed in appropriate packing for ETO
2. Packing must have ETO indicators to confirm that the ETO process has been completed
3. The packing should be labelled with details of the catheter and number of times it has been used.

ETO Process

1. Entire process as per ETO system manufacturer must be followed
2. Complete dwell time for ETO must be used
3. Adequate time and processes must be used to ensure that the catheters are detoxified so that residual ETO is within safe limits.[7]

RECOMMENDATIONS

Based on available literature and consensus between the committee members, the Pak HRS Task Force for reusing electrophysiology catheters recommends the following;

1. Each institution should ensure that the sterilization equipment, personnel and policies as described in this document are in place.
2. The task force recommends that each catheter be used a maximum of 10 times.

3. Cleaning and sterilization should as a minimal follow the processes described in this document.
4. Catheters can be used past the expired date provided they are appropriately resterilized.
5. A mechanism should be in place to report any patient adverse effect attributable to reprocessed catheters.

CONCLUSIONS

These task force recommendations for reusing catheters have tried to balance safety with accessibility for majority of patients in Pakistan. If institutions with electrophysiology services develop adequate policies and SOPs based on these guidelines, arrhythmia patients all over the country will have access to an affordable and safe curative procedure. The task force strongly feels that Cardiac Electrophyisology Speciality would become non-viable in Pakistan unless reprocessed catheters are used.

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Disclaimer: *These recommendations are written in best of shared professional knowledge and experience of the Pakistan Heart Rhythm Society task force members and all members agree to be accountable for all aspects of work ensuring integrity and accuracy.*

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