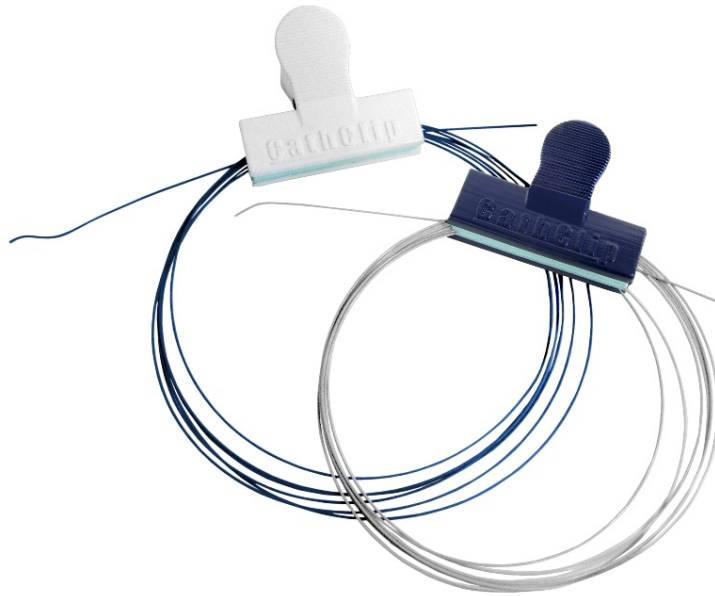


CathClip

guidewire, catheter, and balloon management tool



White Paper –

Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety When Used In Complex Cases Only

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1. Introduction

CathClip – the universal guidewire, catheter, and balloon management tool – saves costs (materials and time), improves clinical outcomes, and improves patient and worker safety by reducing the incidence of replacement guidewires, catheters, and balloons that must be used in procedures when guidewires, catheters, and balloons are damaged or contaminated due to mismanagement of those devices during a procedure.

Guidewires, catheters, and balloons are typically reused throughout entire procedures, with no need for replacement devices. However, if a device is damaged or contaminated (falls outside of the sterile field) during a procedure such that it can no longer function as needed, a replacement device must be used. The replacement device represents an additional cost which otherwise would not have been incurred.

2. Methodology

Data in the form of lists of the materials used in each Interventional Radiology case at a major academic hospital was collected for a period of two months (November and December 2014). Patient information was deidentified. The lists were sorted and replacement materials, including duplicates in each case, were noted. Pricing information was collected for all replacement materials from each replacement material's manufacturer.

For each procedure, there is a standard set of materials that is usually used. Therefore, the materials lists tell a story of what went on in each particular case. By examining the materials lists, it can be determined what type of procedure was being performed and conclusions can be drawn from the materials listed. This includes whether a case was complex or not.

Because guidewires, catheters, and balloons are re-used during procedures, certain devices should not be repeated in a list, nor should there be any devices similar to those devices. Where such a device is repeated, or where there is a device listed that is similar to such a device, it can be deducted that the repeated or similar device was a replacement device that had to be used because the first such device used was damaged or contaminated.



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3. Summary of Data on Cath Lab Materials Usage

The data examined revealed that replacement devices were used in a substantial proportion of procedures, amounting to significant added costs. See *White Paper – Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety*, September 2017 (the “2017 Cost Savings White Paper”).

This data was further examined in complex cases as a subset of all cases, revealing that replacement devices were used in a greater proportion of complex cases only as compared to all cases together, amounting to more significant added costs in complex cases only as compared to all cases together.

CathClip protects guidewires, catheters, and balloons from damage by gently and securely holding any such device. This leads to a decrease in the number of replacement devices used, resulting in the following benefits when the total cost of replacement devices is considered:

- Decreased materials costs (lower facility costs),
- Decreased procedure time (lower facility costs),
- Decreased sedation time due to decreased procedure time (improved clinical outcomes),
- Procedure team can focus on patient care (improved clinical outcomes), and
- Decreased levels of unnecessary radiation (improved patient and worker safety).

4. Detail of Data on Cath Lab Materials Usage

4.1. Replacement devices were used in a substantial proportion of procedures.

All 680 cases over the 2-month period observed were grouped into procedure type as follows:

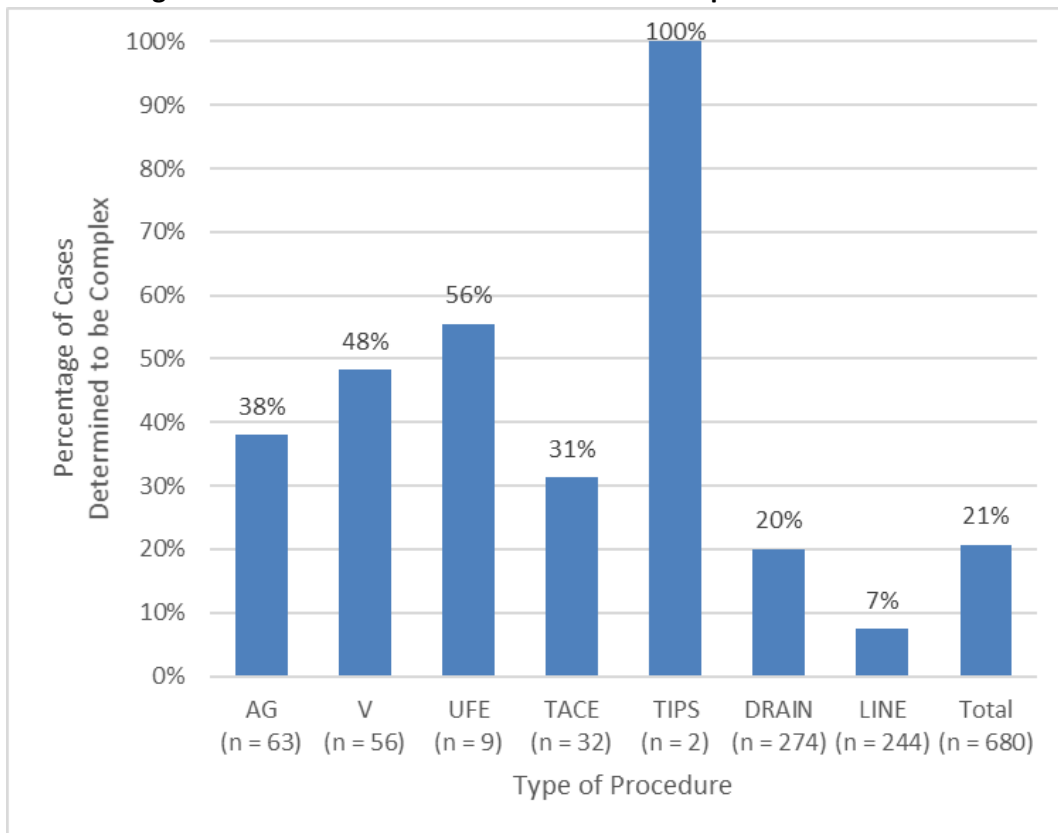
Procedure Type Label	Label Description
AG	Arterial Angiogram and Interventions
V	Venous Interventions, including Arteriovenous Fistula, Arteriovenous Graft, Dialysis Catheter Placement, IVC Filter Placement or Removals, Venous Recanalizations, Pulmonary Embolism Thrombolysis, Transjugular Liver Biopsies, and Gonadal Vein Embolizations
UFE	Uterine Fibroid Embolizations
TACE	Transarterial Chemoembolizations
TIPS	Transjugular Intrahepatic Portosystemic Shunts
DRAIN	Nephrostomy, Biliary, and Abscess Drain Interventions
LINE	Mediport, Hickman, and Dialysis Catheter Interventions



All 680 cases were further classified as complex or routine. Out of 680 cases over the 2-month period observed, 141 cases were determined to be complex cases.

The graph below illustrates the proportion of cases in each procedure type category which were determined to be complex.

Graph 1. Percentage of cases which were determined to be complex.



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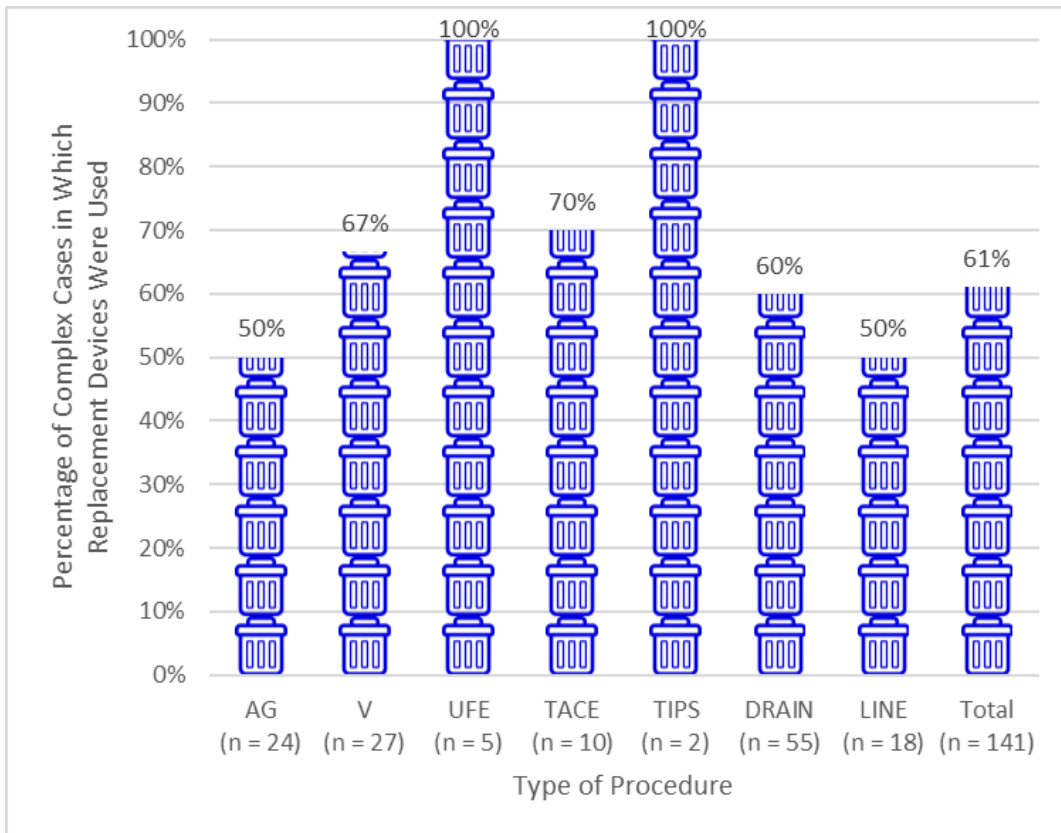


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The proportion of complex cases in which replacement devices were used was greater than the proportion of all cases in which replacement devices were used (61% of complex cases versus 17% of all cases). Cf. 2017 Cost Savings White Paper.

The graph below illustrates the proportion of complex cases in each procedure type group in which replacement devices were used.

Graph 2. Percentage of complex cases in which replacement guidewires, catheters, or balloons were used.



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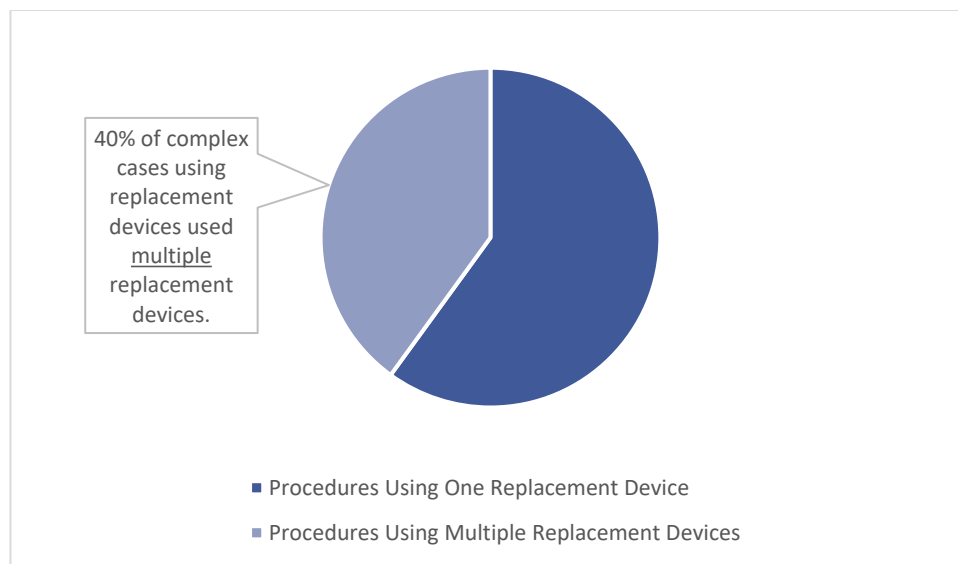
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In 40% of complex cases in which replacement devices were used, more than one (multiple) replacement devices were used (versus 31% of all cases in which replacement devices were used). Cf. 2017 Cost Savings White Paper. This illustrates how the cost of replacement devices can add up even more quickly in complex cases, as compared to all cases. However, the cost of replacement devices also adds up quickly in all cases. This may reflect that not only complex cases, but also routine cases, may lead to multiple replacement devices when using make-shift guidewire, catheter, and balloon management techniques, rather than CathClip, thereby increasing costs and procedure duration.

Graph 3. Percentage of complex cases in which multiple replacement guidewires, catheters, or balloons were used.



4.2. The materials cost of replacement devices is significant.

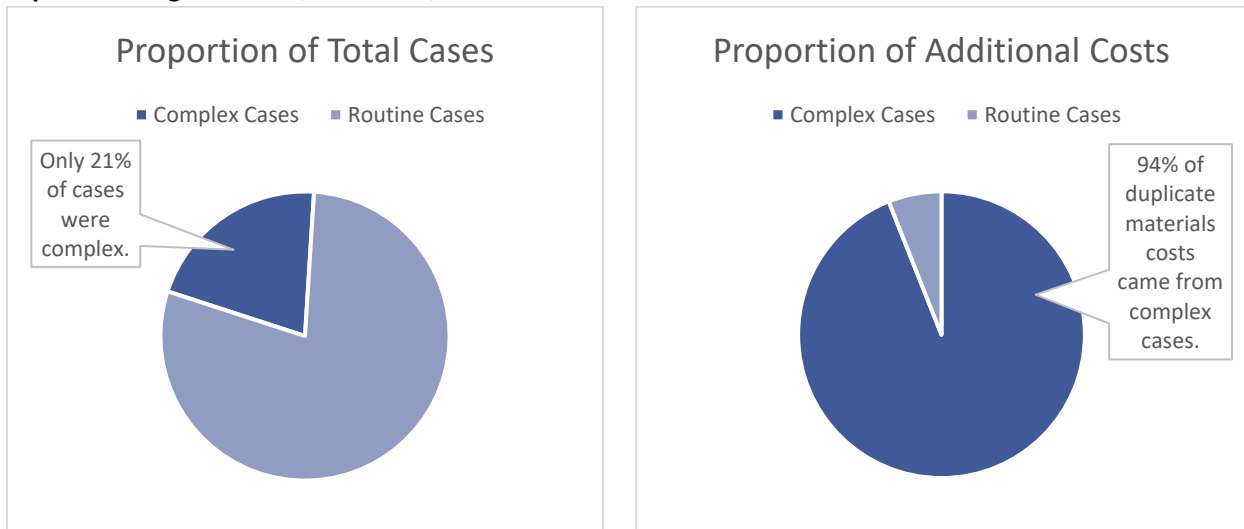
The cost of replacement devices observed was significant, although the data analyzed was only for Interventional Radiology procedures, within a single institution. Overall, 170 replacement guidewires, catheters, and balloons were used over the course of the 2-month period observed. These extra replacement devices ranged in price from \$28.05 to \$2,600.00. The replacement devices used over the course of the 2-month period observed totaled over \$32,000. Over the course of a year, the projected extra cost of replacement devices is over \$196,000. The extra cost per case, in the cost of replacement devices alone, is over \$48. There are additional costs in increased procedure time as well.

In complex cases alone, 141 replacement guidewires, catheters, and balloons were used over the course of the 2-month period observed. These extra replacement devices ranged in price from \$28.05 to \$2,600.00. The replacement devices in complex cases alone used over the course of the 2-month period observed totaled over \$30,000. Over the course of a year, the projected extra cost of replacement devices is over \$180,000 in complex cases only. The extra cost per complex case, in the cost of replacement devices alone, is over \$217. There are additional costs in increased procedure time as well.



While complex cases made up only 21% of all cases, complex cases accounted for 94% of replacement device materials costs.

Graphs 4 and 5. Complex case proportion of total cases and proportion of total additional costs due to replacement guidewires, catheters, or balloons used.



It is important to note that these replacement devices were recorded in procedures only in Interventional Radiology, within a single institution. CathClip is appropriate for use in 9 specialties: Cardiothoracic Surgery, Gastroenterology, Interventional Cardiology, Interventional Nephrology, Interventional Neuroradiology, Interventional Pulmonology, Interventional Radiology, Urology, and Vascular Surgery.

If all 9 specialties are equally busy, with equal rates of complex cases, and if the rate of replacement devices holds across all specialties, the projected extra cost of replacement devices observed throughout the entire institution over the course of the year is over \$1.75 million, \$1.645 million of which is extra costs from complex cases alone.



Total Materials Cost of Replacement Devices Includes Multiple Departments



Data analyzed in this white paper was collected
for Interventional Radiology procedures only.

4.3. The total cost of replacement devices includes the time and effort it takes to retrieve and prepare replacement devices for use (increased costs and negative clinical outcomes).

Each replacement device used also represents an increase in procedure time and a source of distraction during the procedure, in addition to an increase in materials costs.

When a replacement device must be used, time must be taken during the procedure to prepare that new device for use. Of note, many replacement devices are not close at hand within the procedure room – they must be retrieved from the storage area outside of the procedure room by a member of the procedure team. Additionally, the replacement device must be removed from its packaging and prepped for use.

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The total cost of a replacement device, therefore, includes the following costs:

- Increased materials costs (increased cost for the facility),
- Increased procedure time (increased cost for the facility),
- Increased sedation time due to increased procedure time (negative clinical outcomes), and
- Distraction of procedure team from patient care (negative clinical outcomes).

4.4. Replacement devices are evidence of likely unnecessary radiation (patient and worker safety issue).

Flexible elongated device damage for which a replacement device would become necessary (e.g., kinked wire or catheter) is often noticed only when not functioning properly inside of the patient, after everyone in the cath lab or hybrid OR (the patient and the procedure team) has been exposed to unnecessary radiation. With a retrospective study such as this one, it is difficult to assess when this may have happened. However, it is likely that a good number of the 170 replacement devices used over the course of the 2-month period observed (141 replacement devices in complex cases) replaced devices that the operator noted as damaged while inside the patient during the case, resulting in unnecessary radiation to the patient and the team.

4.5. CathClip decreases the incidence of replacement devices, thereby saving costs (materials and time), improving clinical outcomes, and improving safety.

CathClip decreases the incidence of replacement devices because CathClip effectively protects guidewires, catheters, and balloons by holding them gently and securely, eliminating the inefficiencies and the substantial distraction in the cath lab or hybrid OR caused by the use of make-shift techniques to handle those devices. By decreasing the incidence of replacement devices, using CathClip decreases materials costs, decreases procedure time, improves clinical outcomes, and improves patient and worker safety.

5. Conclusion

This study of materials usage in Interventional Radiology cases at a major academic hospital illustrates that the use of replacement devices is common and costly, especially in complex cases. If devices are managed properly, replacement devices are not necessary. CathClip helps properly manage guidewires, catheters, and balloons by holding them gently and securely, thereby protecting these devices from damage. Using CathClip decreases the number of replacement devices needed, resulting in lower facility costs (materials and time), improved clinical outcomes, and improved patient and worker safety, when the total cost of replacement devices is considered.