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Why we should be counting in the cardiac catheter lab: A discussion paper

Abstract

The cardiac catheter laboratory, which in many health care facilities falls under the umbrella of perioperative services, generally sits geographically outside the traditional operating suite. Perhaps due in part to this geographical distance, standards that are routinely applied in the operating suite may not be applied in the cardiac catheter laboratory. One such standard is the management of accountable items such as swabs, surgical instruments, sharps and sheaths. Well-known standards and guidelines for managing accountable items recommend mandatory counting and documentation of all accountable items in environments where a surgical item may be left behind; yet, despite this, counting is not mandatory in the cardiac catheter laboratory.

The risk of items (or parts thereof) being unintentionally retained during percutaneous procedures, such as those performed in the cardiac catheter laboratory, are low; however, this complication still occurs, with several case studies reporting broken and fragmented surgical instruments and/or equipment being retained in patients following procedures.

As the complexity of percutaneous cardiac catheter laboratory cases increases, so does the potential requirement of reversion to open procedures should a serious complication occur; and this, in turn, is known to increase the risk of a surgical item being retained during the subsequent procedure. Performing surgical counts in the cardiac catheter laboratory would improve patient safety during the intra-procedural/intra-operative period by reducing the risk of a surgical item (or parts thereof) being unintentionally left behind, a complication that is likely to result in patient harm.

This discussion paper aims to not only highlight the vital importance of performing a full surgical count of all items used during cardiac catheter laboratory procedures but also to advocate for pre- and post-procedural inspection of sheaths, angioplasty balloons, stents and wires to ensure they are intact at the beginning and end of the procedure. These pre- and post-procedural inspections are vitally important, not just in the cardiac catheter laboratory but in all other areas, such as operating suites, endoscopy and interventional radiology, where endovascular devices are used.

Keywords: unintentional retained items, foreign objects, cardiac catheter laboratory, perioperative nursing, surgical count standards, unintentional retention of foreign object

Introduction

In recent years there has been a huge increase in the use of percutaneous endovascular procedures such as those performed in the cardiac catheter laboratory (commonly known as the cardiac cath lab). This, in turn, has increased the risk of unintentional intra-operative fragmentation and retention of parts of catheters and or sheaths.[1] Adverse events associated with these occurrences may include medicolegal and financial burdens, due to sequela such as sepsis, vessel perforation, thrombosis, embolism, cardiac arrhythmias and death.[2]

Accountable items can be defined as items that 'are at risk of being inadvertently retained in the patient'.[3, p.12] Scholarly literature refers to any medical product that is left behind accidentally in a patient in a perioperative setting as an unintentionally retained surgical item (RSI) but in literature about cardiac catheter laboratories the term 'unintentional retention of a foreign object' (URFO) may also be used. In this discussion paper the term RSI will be used.

A surgical count is an audible, manual process that should follow a consistent methodology in all surgical procedures and use a standardised template for documentation.[3] Items that should be counted include, but are not limited to, swabs, surgical instruments, sharps, sheaths, wires, balloons and stents.

Perioperative nurse education extends to the cardiac cath lab – nurse educators may work in subsidiary areas, such as the cardiac cath lab and medical imaging departments, where interventional procedures are undertaken[4] – so it stands to reason that interventional surgical safety standards may also extend to the cardiac cath lab. However, as far as the authors understand, a surgical count is not routinely conducted in all cardiac cath labs for percutaneous procedures in Australia.

Following extensive review of scholarly literature, it is clear there is a paucity of research specifically investigating RSIs and surgical count processes in the cardiac cath lab. Therefore, this paper draws conclusions from relevant standards and both salient and recently published case studies from this specialist area as well as literature from operating theatres, interventional radiology and endoscopy.

Discussion

In many health care facilities, procedures performed in the cardiac cath lab fall under the umbrella of perioperative services, despite often being geographically located outside the operating suite. Perhaps due in part to this physical distance, standards that are routine in the operating suite may not be applied in the cardiac cath lab.

This discussion will be presented under three themes that emerged from extensive reading of scholarly literature, guidelines and standards relevant to the cardiac cath lab. These themes are 'guidelines and standards pertinent to the cardiac catheter laboratory', 'unintentionally retained items during cath lab procedures' and 'potential for emergency open heart surgery in the cardiac cath lab'. Recommendations for future perioperative practice in the cardiac cath lab will also be made.

Guidelines and standards pertinent to the cardiac catheter laboratory

The New ACORN Standards[3,4] identifies the accepted level of clinical and professional practice in a variety of perioperative and procedural environments. Given that the cardiac cath lab is a procedural environment[5] it is reasonable to expect that cardiac cath labs should comply with ACORN standards.

It is well documented in research literature that appropriately conducted surgical counts play a critical role in the safety of patients during the intra-operative period, and specifically in the prevention of RSIs.[6,7] For over ten years, studies have presented evidence of the safety advantages of using an approved counting process. Norton et al.[8] suggest that the first line of defence in preventing RSIs is a thorough surgical count process. Following the realisation that the retention of items during surgery was one of eight reportable sentinel events, ACORN developed a standardised and structured surgical count process where perioperative nurses perform a minimum of two surgical counts using a structured counting technique.[7] Fencl et al.[5] state that the Association of periOperative Registered Nurses (AORN) RSI prevention guidelines used in the United States of America specifically mention the prevention of device fragments as part of the surgical count process. This is of relevance to the cardiac cath lab due to the use of catheters and sheaths for all procedures. This differs slightly from the ACORN Accountable items standard that does not specifically mention device fragments.

Unintentional retention of foreign objects during cardiac catheter laboratory procedures

The risk of URFO or RSI during coronary angiogram procedures, is considered low[9]; however, this does not negate the requirement to perform surgical counts and careful inspection of devices. This is evidenced by several case studies that report on items unintentionally retained during cath lab procedures.

Endicott et al.[1] discuss a recent report that looked at 308 sentinel events over a six-year duration. Of these events, 28 involved cardiac, angioplasty or thrombolysis catheters, and 68 per cent involved broken fragments or parts,[1] highlighting the inherent risk of RSI.

In a case report by Ghazala et al.[10] a patient suffered a severe infection because a macroscopic fragment of a radial artery sheath was retained. Again, while this case may be a rare complication, it highlights the possibility of RSI during cath lab procedures. In keeping with the AORN guideline, Ghazala et al.[10] also recommend that sheaths and other devices are routinely and thoroughly inspected pre-procedure and upon removal. The close visual inspection of surgical instruments and equipment has been shown to limit the risk of surgical items being retained.[6]

Idhrees et al.[11] described a case where a patient suffered left ventricular dysfunction due to the retention of a fractured guidewire in the left anterior descending artery (LAD) causing a total occlusion of the LAD. In this case, the fragmented guide wire went unnoticed for two years with the patient presenting with only angina on exertion; however, the potential was there for this type of complication to have become life-threatening.

In 2012, Goldberg and Feldman[12] recommended adding items and devices with the potential to fracture or become fragmented to the count sheet as a reminder to the team of the possibility of RSI. This recommendation has been further echoed by more recent authors,[6,10] who also hoped to prompt careful visual inspection of devices to ensure that items documented on the count sheet are intact, and items that are not intact are immediately investigated. However, a count sheet is not routinely used during percutaneous procedures in Australian cardiac cath labs; and, despite the recommendations mentioned above, routine counts and careful inspection of endovascular devices before and after procedures may still be suboptimal in some cardiac cath labs and operating suites.

If a percutaneous or endovascular device fragments and a portion is unintentionally retained, measures need to be instigated to remove the fragment and this may result in emergency surgery. Idhrees et al.[11] stated that the retention of a fractured guidewire, is likely to result in emergency surgery for 20 per cent of patients who experience this complication. Additionally, even in non-urgent scenarios, surgical removal of iatrogenic foreign bodies may pose less risk than percutaneous intervention due to the potential of causing further vascular injury with repeated percutaneous attempts.[11]

The potential for emergency open surgery in the cardiac cath lab

Case studies have reported instances where emergencies in the cardiac cath lab have required urgent transfer to the operating suite for emergency surgery.[13,14] Waiker et al.[13] and Kar et al.[14] describe cases where their respective patients required urgent removal of retained broken angioplasty balloon catheters from their coronary artery. While this is an emergency requiring urgent surgery, it may not always be possible to secure a cardiac operating theatre in a timely manner. In these very rare situations, when patients are significantly unstable, open-heart surgery has been performed in the cardiac cath lab.

Such a scenario was reported in a case study by Gajjar et al.[15] where emergency open surgery was performed in the cardiac cath lab for a patient who developed a life-threatening cardiac tamponade following accidental perforation of the right atria with a guide wire during a mitral valvuloplasty. The patient subsequently required a right thoracotomy to relieve the tamponade, repair the atria and surgically repair the mitral valve.[15] In this example, the surgery was performed in the cardiac cath lab due to the patient's sudden and continuing deterioration and the immediate unavailability of a suitable operating theatre.[15]

While this case does not specifically examine surgical counts, it does demonstrate the possibility of percutaneous procedures resulting in emergency open surgery occurring within the cardiac cath lab.[15] If this rare situation should arise, and counting and visualisation of surgical instruments, including needles, sheaths, guide wires, stents and balloons, is not conducted at the start of the percutaneous procedure, the risk of RSI during the open procedure increases as does the possibility that an RSI may go unnoticed and unmanaged. As part of standard

operating theatre procedure, a count should be undertaken by the perioperative cardiothoracic nursing team at the commencement of the open procedure and documented on a standardised count sheet. The second open count should also incorporate and document the initial counts from the percutaneous procedure as per ACORN's Accountable items standard.[3] However, this practice could not occur if an initial count was not performed and documented on a standardised count sheet for all percutaneous cardiac cath lab procedures.

In a meta-analysis regarding risk factors for RSI conducted by Moffatt-Bruce et al.[16] it was concluded that unexpected intra-operative factors such as more than one procedure, the involvement of more than one team, and the lack of a surgical count were variables that increased the risk of RSI.

In 2014 Braham et al.[17] stated that cardiac cath lab patients having complex procedures, such as transcatheter aortic valve implantation and mitral valve clipping, have been deemed at high risk for open surgery due to their comorbidities as well as the complexity of the procedure. In 2018 an observational study over ten years by Ezad et al.[18] reported a low incidence (0.1%) of emergency surgical intervention for cardiac cath lab procedures. However, they also stated that although urgent surgical intervention of cardiac cath lab procedure complications are uncommon, as procedures performed in this specialist area become more complex the emergency surgery rate is an ongoing potential risk.[18] In 2020, Kirov et al.[19] concurred and attributed a trend upwards in complications to the increasing complexity of cardiac cath lab procedures. Finally recent literature by Waikar et al.[13] again reported that while the introduction and use of new procedures and equipment in the cardiac cath lab has largely been very successful it has also led to increased complication rates that have greater potential to require emergency surgery.

Hybrid cardiac cath labs are now commonly used, specifically to accommodate more complex procedures that will require the sterility of operating theatres and may require open surgical access with anaesthesia.[20] This recognition that increasing complexity of cardiac cath lab procedures require hybrid laboratories should include the requirement to follow surgical count standards and guidelines to improve patient safety by mitigating the risk of RSI.

Conclusion

Over time, percutaneous endovascular procedures have become more complex thus increasing the risk of conversion to open heart surgery, unintentional intra-operative fragmentation and retention of parts of catheters and/or sheaths in a patient. Standards and guidelines do exist to reduce the risk of RSI and suggest that the use of a standardised counting process, inspection of devices (including sheaths, angioplasty balloons, stents and wires) before and after a procedure, and recording this information on a standardised count sheet is warranted and should be undertaken in any area where an open, percutaneous or endoscopic procedure is undertaken.

The primary recommendation of this discussion paper is that any department using percutaneous and/or endovascular devices – such as operating suites, endoscopy units and interventional radiology – not only perform a full surgical count, using a standardised count sheet to document accountable items, but also ensure that they conduct a careful inspection of sheaths, angioplasty balloons, stents and wires before and after a procedure. If these inspections are not conducted, literature informs us that an RSI can go undetected, often for long periods of time, and possibly cause preventable adverse events such as sepsis, vessel perforation, thrombosis, embolism, cardiac arrhythmias and death.

Due to an increase of percutaneous and endovascular procedures being performed in locations that are considered a 'perioperative environment', a secondary recommendation of this paper is that ACORN gives serious consideration to revising their Accountable item standard to include the inspection of sheaths, angioplasty balloons, stents and wires before and after procedures, and the recording of this information on the standardised count sheet.

As there is a paucity of research into this topic and, to date, there has been no research conducted in the Australian setting, it is also recommended that further research be undertaken. As this practice is initiated in the Australian setting, perhaps consideration should be given to research in the form of pre- and post-implementation studies.

Given that the highest level of patient safety should be the aim of all nurses and health professionals, surely it is time to apply counting and observational safeguards to all patients who undergo a surgical procedure, no matter the location.

Declaration of conflicting interests

The authors have declared no competing interests with respect to the research, authorship and publication of this article.

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