MOH/P/PAK/473.21(TR)-e

TECHNOLOGY REVIEW (MINI-HTA)

MOBILE C-ARM FLUOROSCOPY FOR CARDIOTHORACIC SURGERY

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
007/2021

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Available online via the official Ministry of Health Malaysia website: http://www.moh.gov.my

e-ISBN:978-967-2887-24-9

SUGGESTED CITATION: Fatin NM, Ana FAS and Izzuna MMG. Mobile C-Arm Fluoroscopy for Cardiothoracic Surgery. Technology Review. Ministry of Health Malaysia: Malaysian Health Technology Assessment Section (MaHTAS); 2021. 32 p. Report No.: 007/2021. e-ISBN:978-967-2887-24-9

DISCLOSURE: The author of this report has no competing interest in this subject and the preparation of this report is entirely funded by the Ministry of Health Malaysia.

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EXECUTIVE SUMMARY

Introduction

Cardiothoracic surgery is the field of surgery pertaining to cardiovascular (heart and blood vessel) and pulmonary (lung) surgery. It is used to diagnose and treat diseases and traumatic injuries of the heart, lungs, and other allied structures, such as the trachea (windpipe), esophagus (feeding tube), and diaphragm. The type of surgical involves is diverse, including coronary artery bypass surgery, lung resection, vascular stenting, and many other procedures like thoracic surgery.

A few common cardiothoracic surgeries and procedures include angioplasty, stent placement, ablation, pacemakers and implantable cardioverter defibrillators, ventricular assist devices, heart transplant, thoracic endovascular aortic repair (TEVAR), transfemoral/ transapical aortic valve replacement (TAVI/ TAVR) and carotid surgery.

<u>Mobile C-arm Fluoroscopic System</u>

A mobile C-arm fluoroscopic system is an alternative option instead of building a new hybrid operating room. The system is used for a variety of diagnostic imaging and minimally invasive surgical procedures. In the operating room, the system helps in visualising kidney drainage, abdominal and thoracic aortic aneurysm repair, percutaneous valve replacements, cardiac surgery, vascular surgery, gastroenterology, neuro stimulation, orthopaedics, pain management and neurology procedures.

This technology review was requested by the Cardiothoracic Surgery Department, *Hospital Pulau Pinang*, to provide the best available evidence related to the mobile C-arm fluoroscopic system for cardiothoracic surgery.

Objective/aim

To evaluate the efficacy, safety, cost-effectiveness and organisational issues related to the mobile C-arm fluoroscopic system for cardiothoracic surgery.

Results and conclusions

A total of 595 titles were retrieved. After removing duplicates, applying inclusion and exclusion criteria, finally three studies were included in this review. Three studies included, comprised of one prospective, single-centre, randomised controlled trial, one case study and one pilot study.

There were limited evidence retrieved on efficacy, safety, cost and organisational issue related to mobile C-arms fluoroscopy for cardiothoracic surgery. The evidence showed that this system had a potential to float and position safely a pulmonary artery catheter in a shorter time. Moreover, the mobile C-arm may be used to confirm the location of microcoil while performing a thoracoscopic surgery without the need to transfer the patient to any other room.

In terms of safety, the evidence on the mobile C-arm fluoroscopy showed that the malposition and cardiac arrhythmias was lesser when this system was used. Furthermore, there were various mobile C-arm fluoroscopy registered with the Medical

Device Authority. The mobile C-arm fluoroscopy also had received 510(k) from United States Food and Drug Administration.

Meanwhile, in terms of cost, the range of price of mobile C-arm fluoroscopy was from $15,000 to $130,000 (RM62,767.5 to RM543,985) regardless of the product brands and manufacturers.

As for organisation aspect, the system requires an adequate operating room size, along with the sufficient existing infrastructure, and needs to be operated optimally.

Methods

Electronic databases were searched through the Ovid interface; Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to 27 July 2021, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to July 27, 2021, Ovid MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations 1946 to July 27, 2021, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 2017 to July 27, 2021, • Ovid MEDLINE(R) 1946 to July Week 3 2021, Ovid MEDLINE(R) 1996 to July Week 3 2021, Ovid MEDLINE(R) Epub Ahead of Print July 27, 2021, Ovid MEDLINE(R) Daily Update July 27, 2021 and Ovid MEDLINE(R) 2017 to July Week 3 2021. Searches were also run in PubMed, INAHTA, Cochrane Library and US Food and Drug Administration. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 2 August 2021.

TABLE OF CONTENTS

ABBREVIATIONS

ACS	Acute coronary syndrome
CAD	Coronary artery disease
CASP	Critical Appraisal Skills Programme
Cath Lab	Catheterisation laboratory
COVID-19	Coronavirus disease 2019
EVAR	Endovascular repair
IEC	International Electrotechnical Commission
IQR	Interquartile range
LVRS	Lung volume reduction surgery
MSA	Multiple system atrophy
NCVD	National Cardiovascular Disease Database
ROB	Risk of bias
ROI	Return on investment
RSA	Radiostereometric analysis
SD	Standard deviation
TAVR/TAVI	Transfemoral/ transapical aortic valve replacement
TEVAR	Thoracic endovascular aortic repair
US	United States

1.0 BACKGROUND

Cardiothoracic surgery is the field of surgery pertaining to cardiovascular (heart and blood vessel) and pulmonary (lung) surgery. It is used to diagnose and treat diseases and traumatic injuries of the heart, lungs, and other allied structures, such as the trachea (windpipe), esophagus (feeding tube), and diaphragm. The type of surgery involves is diverse, including coronary artery bypass surgery, lung resection, vascular stenting, and many other procedures like thoracic surgery.[1]

Open Surgery versus Minimally Invasive Surgery

In early years, open cardiothoracic surgery is the only way to conduct the operation. Technically, open cardiothoracic surgery refers to any surgical procedure in which the chest is surgically opened. This type of surgery requires a six to eight-inches incision in the chest and may involve temporary placement of a pacemaker to help regulate the heartbeat. The patient will likely remain in the hospital for four to eight days after open surgery, and it may take at least five to eight weeks to recover.[2]

Minimally invasive surgery was introduced in 1990s. In minimally invasive cardiothoracic surgery, the surgeon will make one or more small incisions between the ribs. Patient who undergone minimally invasive surgery returns home two to five days after the procedure. In general, it takes between one and four weeks to recover from this surgery. Due to a smaller incision, minimally invasive surgery may benefits patients with less pain, less scarring and lower risk of infection and bleeding.[2] Some examples of the minimally invasive procedures are direct coronary artery bypass, transfemoral/ transapical aortic valve replacement (TAVI/ TAVR), atrial fibrillation ablation, transcatheter aortic valve replacement, percutaneous indirect mitral annuloplasty, mitral-valve surgery, hybrid coronary revascularization and thoracic endovascular aortic repair (TEVAR).[3]

Rooms Associated with Minimally Invasive Surgery

a. Cardiac Catheterisation Laboratory (Cath Lab)

A cardiac catheterisation laboratory, also known as a “cardiac cath lab,” is a special hospital room where doctors perform minimally invasive tests and procedures to diagnose and treat cardiovascular disease. The procedures performed in a cardiac cath lab almost always involve tiny, flexible tubes, called catheters, to access the heart and blood vessels. A cath lab has special imaging equipment used to visualise the arteries and monitor blood flow to and from the heart. This information helps the care team to diagnose and treat blockages and other problems in the arteries.[4]

According to the Summary of the Annual Reports of the National Cardiovascular Disease Database (NCVD) – Acute Coronary Syndrome (ACS) Registry 2006 – 2015, the number of hospitals with cardiac cath lab in Malaysia is 73; 58 in the public sector while 15 in the private sector.[5]

b. Hybrid Operating Room

A hybrid operating room is an advanced procedure space that combine a traditional operating room with fixed advanced imaging systems, offering the capability to perform combined image-guided procedures with minimally invasive procedures. These state-of-the-art spaces also allow for the combination of image guided surgery with open procedures.[6] The hybrid operating room facilitates conversion to open surgery if required to minimally invasive surgery.[7]

The typical cost of building a hybrid operating room is approximately 120% more than a traditional surgical operating room. The operating costs for each hybrid operating room adds 90% to standard operating room costs.[8] The installation costs range from US $1.2 million to $5.0 million depending on the devices that are installed.[9] This capital investment expense is compounded by ongoing equipment maintenance expenditures and an equipment lifecycle that would typically be shorter than that of a traditional operating room. Moreover, because the space requirements are substantially greater for the hybrid operating room than a standard operating room or cath lab, this has the potential to parasitise the space of one of these locations. The return on investment depends on the growth of the hybrid program. There has been reported increase in cases after building a hybrid operating room, even though this can be unpredictable. In some cases, volume increases are likely a result of marketing effect and, though this may not be sustained, the Cleveland Clinic Foundation showed that the investment was returned in just over two years.[10] Smaller hospitals may find it challenging to completely fill the hybrid operating room schedule with one team's cases, and effectively dividing the utilisation among multiple services will allow more efficient use of the hybrid operating room.[11]

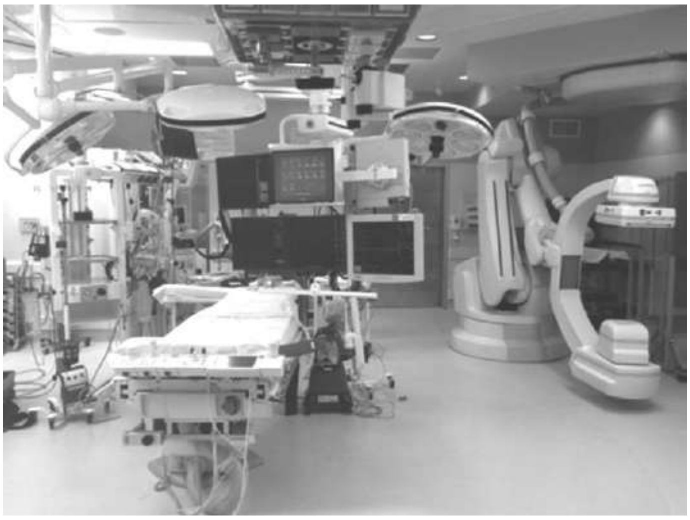

Figure 1: Hybrid operating room. Floor mounted c-arm in the right, surgical monitor and table in the middle, and anesthesia machine in the deep left.[11]

Mobile C-arm Fluoroscopic System

A mobile C-arm fluoroscopic system is an alternative option instead of building a new highly cost hybrid operating room. The system is used for a variety of diagnostic imaging and minimally invasive surgical procedures. In the operating room, the system helps in visualising kidney drainage, abdominal and thoracic aortic aneurysm repair, percutaneous valve replacements, cardiac surgery, vascular surgery, gastroenterology, neuro stimulation, orthopaedics, pain management and neurology procedures.[12]

This technology review was requested by the Cardiothoracic Surgery Department, *Hospital Pulau Pinang*, to provide the best available evidence related to the mobile C-arm fluoroscopic system for cardiothoracic surgery.

2.0 OBJECTIVE/ AIM

To evaluate the efficacy, safety, cost-effectiveness and organisational issues related to the mobile C-arm fluoroscopic system for cardiothoracic surgery.

3.0 TECHNICAL FEATURES

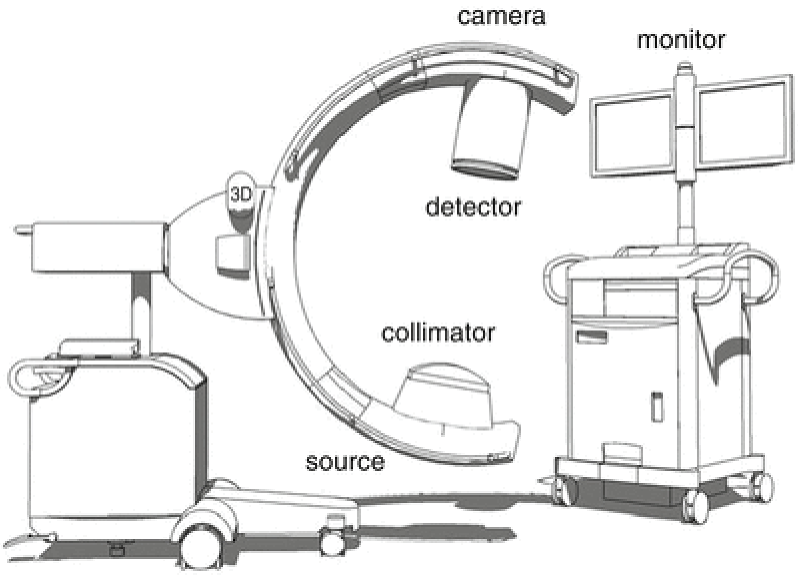

Figure 2: Basic components of a mobile C-arm fluoroscopic system.[13]

There are two main configurations of permanently installed fluoroscopic systems. One class commonly utilises a radiolucent patient examination table with an under-table mounted tube and an imaging system mounted over the table. The other is commonly referred to as a C-arm system that is used where greater flexibility in the examination process is needed.[14]

A C-arm is an imaging scanner intensifier. The name derives from the C-shaped arm used to connect the X-ray source and X-ray detector to one another. C-arms have radiographic capabilities, though they are used primarily for fluoroscopic intraoperative imaging during surgical, orthopaedic and emergency care procedures. The devices provide high-resolution X-ray images in real time, thus allowing the physician to monitor progress and immediately make any corrections.[14]

Table 1: The major players of mobile C-arm system in the market (last updated on 7 July 2021)[15]:

Manufacturer	**Product**
GE Healthcare	OEC 3D
	OEC Elite CFD
	OEC One CFD
	OEC Elite MiniView
	OEC Elite
	OEC One
Hologic	Fluoroscan InSight FD
Orthoscan	Orthoscan TAU 2020
	Orthoscan TAU 1515
	Orthoscan TAU 1512
	Orthoscan Mobile DI
Philips	Veradius Unity
	BV Pulsera
	Zenition 70
	Zenition 50
Siemens Healthineers	Cios Spin
	Cios Alpha VA30
	Cios Flow
	Cios Select FD VA21
	Cios Select I.I VA21
Turner Imaging Systems	Smart-C
Ziehm Imaging	Ziehm Vision RFD 3D CMOSline
	Ziehm Vision RFD Hybrid Edition CMOSline
	Ziehm Solo FD CMOSline
	Ziehm Vision RFD CMOSline
	Ziehm Vision R
	Ziehm Vision FD (31 x 31)
	Ziehm Vision FD CMOS
	Ziehm Solo

4.0 METHODS

4.1 Searching

Electronic databases were searched through the Ovid interface:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to 27 July 2021
- Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to July 27, 2021
- Ovid MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations 1946 to July 27, 2021
- Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 2017 to July 27, 2021
- Ovid MEDLINE(R) 1946 to July Week 3 2021
- Ovid MEDLINE(R) 1996 to July Week 3 2021
- Ovid MEDLINE(R) Epub Ahead of Print July 27, 2021
- Ovid MEDLINE(R) Daily Update July 27, 2021
- Ovid MEDLINE(R) 2017 to July Week 3 2021

Searches were also run in PubMed, INAHTA, Cochrane Library and US Food and Drug Administration. Google was used to search for additional web-based materials and information. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 2 August 2021.

Appendix 1 shows the detailed search strategies.

4.2 Selection

Two reviewers screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection. The inclusion and exclusion criteria were:

Inclusion criteria

Population	Cardiothoracic surgery
Interventions	Mobile C-arm fluoroscopy
Comparators	Hybrid operating room
Outcomes	**Efficacy:** Time taken to float and position the pulmonary artery catheter balloon, confirmation of the microcoil location, the quality of images **Adverse events:** Ventricular rhythm disturbances, catheter malposition
Study design	Health Technology Assessment (HTA) reports, Systematic Review (SR) and Meta-Analysis, Randomised Control Trial (RCT), Non-randomised Control Trial (RCT), cohort studies, cross-sectional studies, case studies
Type of publication	English, full text articles

Exclusion criteria

Study design	Studies conducted in animals, narrative reviews
Type of publication	Non-English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) checklist and evidence graded according to the US/Canadian Preventive Services Task Force (See **Appendix 2**). Data were extracted from included studies using a pre-designed data extraction form (evidence table as shown in **Appendix 3**) and presented in tabulated format with narrative summaries. No meta-analysis was conducted for this review.

5.0 RESULTS

5.1 Selection of the included studies

A total of 595 titles were retrieved. After removing duplicates, applying inclusion and exclusion criteria, there were three studies reported on mobile C-arm fluoroscopy system were included in this review. The included studies were one prospective, single-centre, randomised controlled trial, one case study and one pilot study as shown in **Figure 5**. The studies were conducted in German, Australia and Canada.

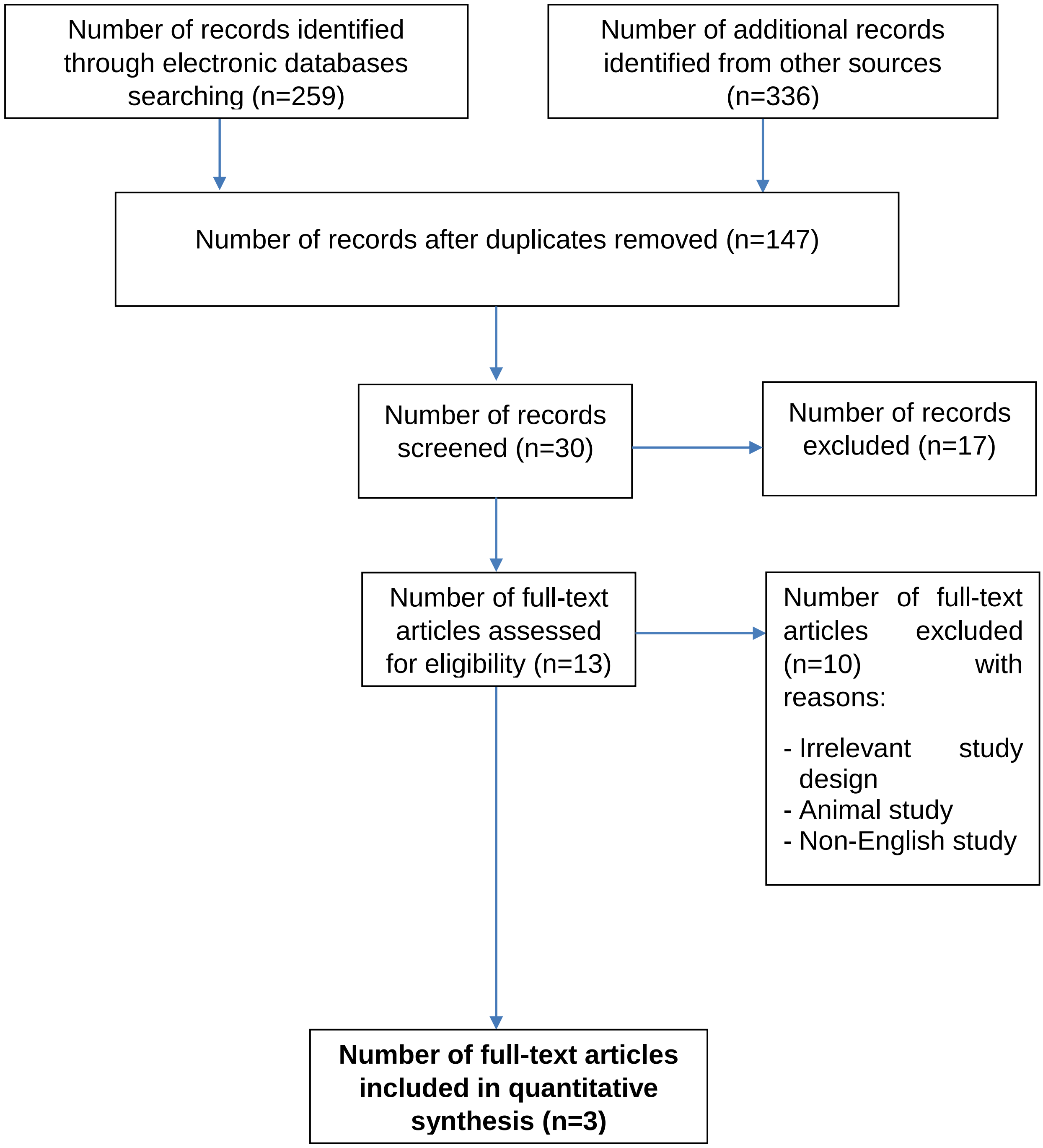

Figure 5: Flow chart of study selection

5.2 Critical appraisal of the included studies

The risk of bias assessment for randomised controlled trial was assessed using Cochrane Risk of Bias Assessment tool (ROB 2.0) reference. Risk of bias assessment of the included study is summarised according to the study design as below.

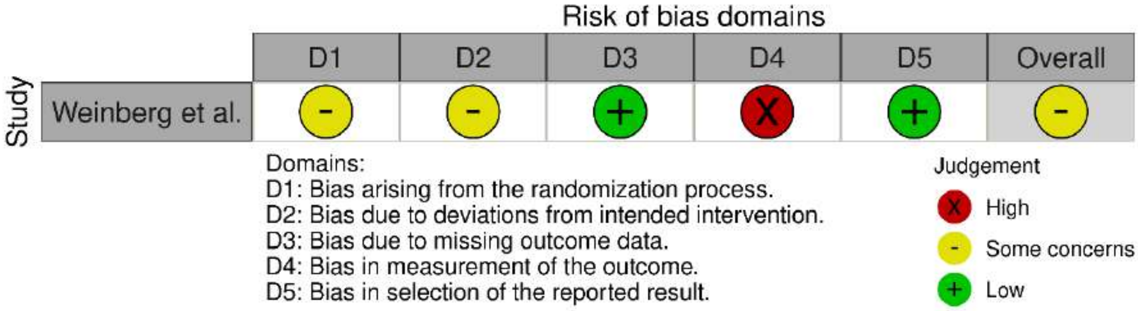

Figure 6a: Assessment of risk of bias of randomised controlled trial (Cochrane ROB 2.0 reference: Traffic Light Plot)

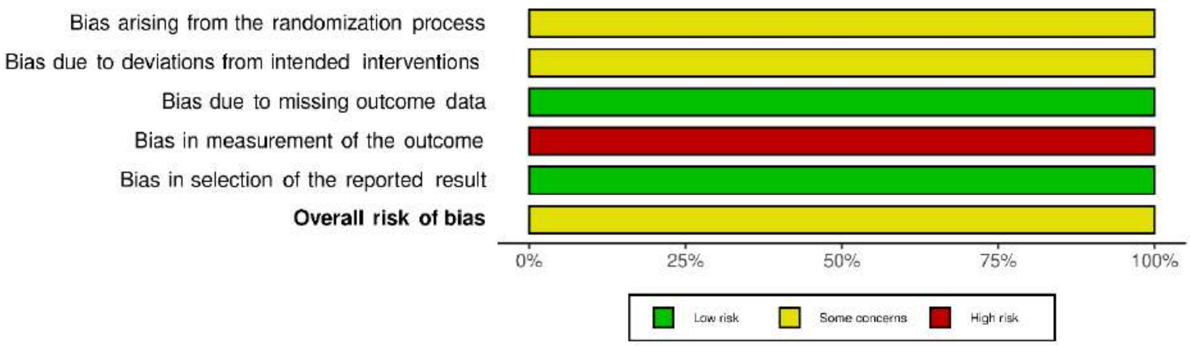

Figure 6b: Assessment of risk of bias of randomised controlled trial (Cochrane ROB 2.0 reference: Summary Plot)

5.3 Efficacy/ Effectiveness

There were three studies on the efficacy of mobile C-arm fluoroscopy, of which one prospective, single-centre, randomised controlled trial, one case study and one pilot study.

A prospective, single-centre, randomised controlled trial by Weinberg et al. (2015) was conducted to determine whether video fluoroscopy combined with traditional pressure waveform analyses facilitated optimal pulmonary artery catheter floatation and final positioning compared with the traditional pressure waveform flotation technique alone. The trial was carried out between July 2010 and July 2012 at a university teaching hospital with complex cardiac surgery experiences. Adult patients considered to be at higher risk for difficult pulmonary artery catheter insertion who were undergoing elective or semi-urgent cardiac surgery that necessitated a pulmonary artery catheter as part of routine perioperative care. Criteria for inclusion were obtained from routine preoperative transthoracic or transesophageal echocardiography, coronary angiography and right heart catheterisation studies.

However, population aged below than 18 years old, no ability to provide informed and written consent (eg: patient awaiting surgery in the intensive care unit who had been administered sedatives), and time-critical surgery in which induction of anesthesia was imperative before the pulmonary artery catheter being inserted were excluded.[16, level I]

Patients were assigned randomly into two groups using a computer-generated program: 25 patients in whom the pulmonary artery catheter was floated using video fluoroscopy combined with real-time pressure waveform monitoring (fluoroscopy group), and 25 patients in whom the pulmonary artery catheter was floated by real-time pressure waveform monitoring along (usual-care group).[16, level I]

Cardiac output measurements were performed via a right heart catheter study in six patients during preoperative cardiac catheterisation. The pulmonary artery catheter was inserted via the right internal jugular vein of all patients.[16, level I]

The trial reported that, the mean (standard deviation [SD]) time to float the pulmonary artery catheter was significantly shorter in the fluoroscopy group; 73s (SD 65.1) versus 176s (SD 180.6) in the usual-care group; p=0.014. Moreover, the median (interquartile range [IQR]) number of attempts to successful floatation was lower in the fluoroscopy group: 1(IQR 1:2) attempts versus 2 (IQR 1:4) attempts in the usual-care group; p=0.007. The author concluded that, in patients considered at higher risk for pulmonary artery catheter-related complications who were undergoing cardiac surgery, video fluoroscopy facilitated faster and safer pulmonary artery catheter floatation and positioning compared with the traditional pressure waveform floatation technique alone.[16, level I]

Ujiie et al. (2017) conducted **a case study** to describe the capabilities of the guided therapeutics system, the first-in-human technologies used and evaluated in guided therapeutics operating room. A hybrid operating room was developed to establish the efficacy of different minimally invasive therapies, known as the guided therapeutics operating room at the Toronto General Hospital. The guided therapeutics operating room was equipped with multi-modality image-guidance systems, which featured a dual source-dual energy computed tomography (CT) scanner, a robotic cone beam CT, fluoroscopy, high-performance endobronchial ultrasound system, endoscopic surgery system, near-infrared, fluorescence imaging system and navigation tracking systems. The study showed that X-ray fluoroscopy was used to confirm the location of the microcoil to carry out the video assisted thoracoscopic surgery. The use of the guided therapeutics operating room allowed the ability to perform a series of surgical procedures without the need to transfer the patient to any other room, ultimately supporting improved workflow throughout the procedure.[17, level III]

A pilot study was conducted by Nollert et al. (2009) to study the integration of interventional techniques into cardiovascular surgery which required angiographic imaging capabilities in an operating room. The imaging modality used was intraoperative 3D imaging with angiography system combined with fluoroscopy. The study reported that, brilliant fluoroscopy images were the predominantly used images during surgery while using smaller radiation dose. However, modern angiography systems offered advanced imaging and post-processing capabilities including image fusion with any type of previously acquired 3D volumes, guidance or 3D imaging.[18]

5.4 Safety

There was one study reported on the safety of mobile C-arm fluoroscopy.

Weinberg et al. (2015) reported that the composite complication rate (malposition and arrhythmias) was greater in the usual-care group than in the fluoroscopy group (52% versus 16%, respectively); p=0.01).[16, level I]

According to the Medical Device Authority, there were various mobile C-arm fluoroscopy registered such as Orthoscan digital diagnostic imaging and fluoroscopy, Ziehm Vision series, OEC Fluorostar series, Siremobil Compact L and Genoray Fluoroscopic X-ray system.[21] The mobile C-arm fluoroscopy also had received 510(k) from United States Food and Drug Administration.[23]

5.5 Cost analysis and cost-effectiveness

There was a comparison of price of several mobile C-arms fluoroscopy in the global market. According to **Figure 7**, the price of mobile C-arm fluoroscopy in the market ranged from $15,000 to $130,000, which was determined by the different level of advancement of the system.[19]

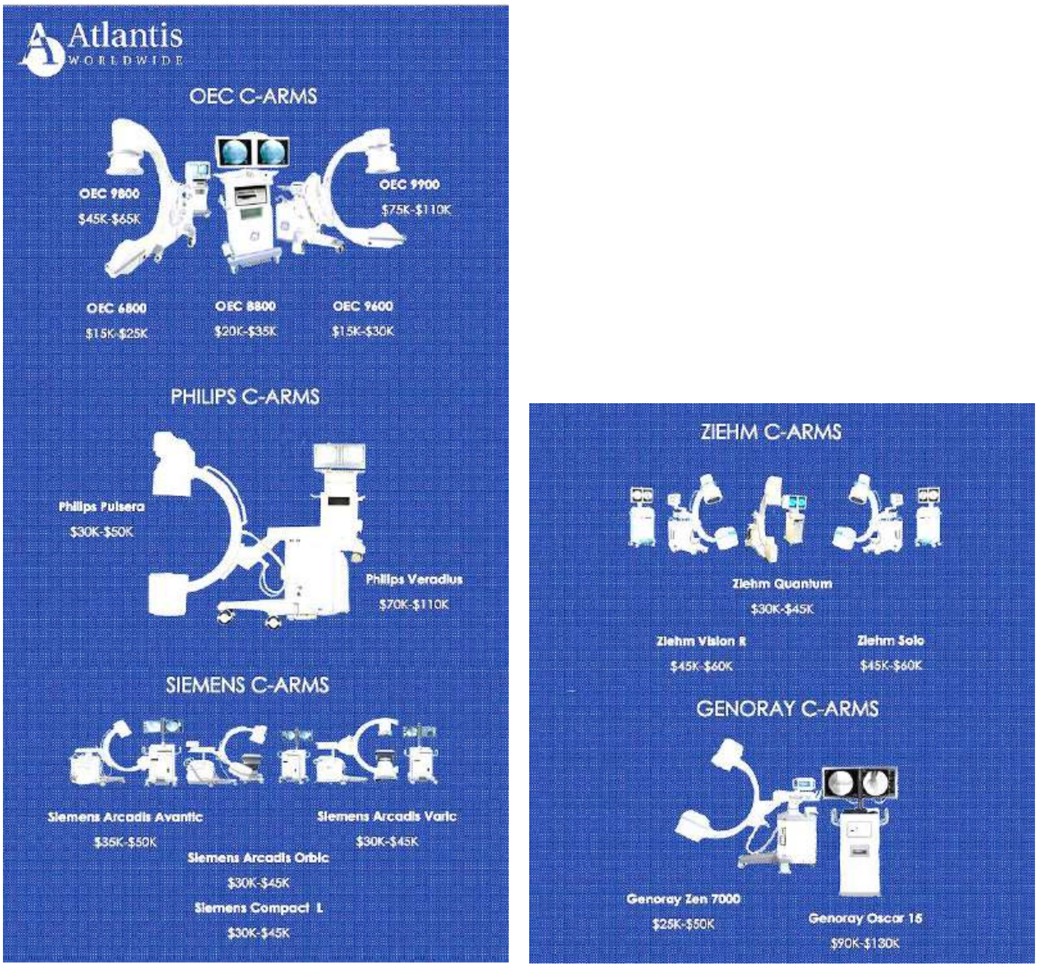

Figure 7: Prices of mobile C-arms fluoroscopy with different manufacturers (Latest update was on March 2021).[19]

The postponement of non-essential elective surgeries and medical procedures in 2020 in order to conserve medical resources for COVID-19 patients during the start of the pandemic, cardiovascular or cardiothoracic procedures were severely impacted. This was expected to result in reduced capital expenditure budgets for imaging equipment, including surgical mobile C-arm X-ray. The world markets for these imaging systems were estimated to have declined by 17.4% for cath lab angiography systems and 16.3% for surgical mobile C-arms in 2020 according to a new report from Signify Research.[20]

5.6 Organisational Issue

The system required an adequate operating room size, along with the sufficient existing infrastructure, and needed to be operated optimally.[22]

5.7 Limitations

This technology review has a limitation. Although there was no restriction in language during the search but only English full text articles were included in this review.

6.0 CONCLUSION

There were limited evidence retrieved on efficacy, safety, cost and organisational issue related to mobile C-arms fluoroscopy for cardiothoracic surgery. The evidence showed that this system had a potential to float and position safely a pulmonary artery catheter in a shorter time. Moreover, the mobile C-arm may be used to confirm the location of microcoil while performing a thoracoscopic surgery without the need to transfer the patient to any other room.

In terms of safety, the evidence on the mobile C-arm fluoroscopy showed that the malposition and cardiac arrhythmias was lesser when this system was used. Furthermore, there were various mobile C-arm fluoroscopy registered with the Medical Device Authority. The mobile C-arm fluoroscopy also had received 510(k) from United States Food and Drug Administration.

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As for organisation aspect, the system requires an adequate operating room size, along with the sufficient existing infrastructure, and needs to be operated optimally.

7.0 REFERENCES

1. Whitlock J. Cardiothoracic surgery: Everything you need to know. 2021. Available at https://www.verywellhealth.com/cardiothoracic-defined-3157055 Accessed on 02.08.2021.

2. Which heart surgery is best?. Heart and Vascular Heart. 2016. Available at https://share.upmc.com/2016/03/heart-surgery-best/ Accessed on 02.08.2021.

3. Iribarne A, Easterwood R, Chan EYH et al. The golden age of minimally invasive cardiothoracic surgery: Current and future perspectives. Future Cardiol. 2011; 7(3): 333–346.

4. What is a cardiac catheterization lab? Second Count. 2014. Available at http://www.secondscount.org/treatments/treatments-detail-2/what-is-cardiac-catheterization-lab#.YRSaG4gzYdV Accessed on 02.08.2021.

5. Summary of the Annual Reportd of the NCVD-ACS Registry 2006-2015. National Cardiovascular Disease (NCVD)-ACS Registry. Ministry of Health Malaysia.

6. What is a hybrid operating room? Steris Healthcare. Available at https://www.steris.com/healthcare/knowledge-center/surgical-equipment/what-is-a-hybrid-operating-room Accessed on 29.07.2021.

7. The cardiovascular hybrid OR-clinical & technical considerations.CTSNet. Available at https://www.ctsnet.org/article/cardiovascular-hybrid-or-clinical-technical-considerations Accessed on 02.08.2021.

8. Neumann FJ. The hybrid suite: the future for percutaneous intervention and surgery?-cost issues. EuroPCR. 2009.

9. Kpodonu J. Hybrid cardiovascular suite: The operating room of the future. J Card Surg. 2010; 25: 704–709.

10. Sronin GM, Shroyer M. Financial aspects of building a hybrid operating suite. American Association for Thoracic Surgery 90th Annual meeting. 2010.

11. Kaneko T & Davidson MJ. Use of the hybrid operating room in cardiovascular medicine. American Heart Association, Inc. 2014; 130: 910-917.

12. Fornell D. An Introduction to mobile c-arm x-ray systems. Imaging Technology News. 2011. Available at https://www.itnonline.com/article/introduction-mobile-c-arm-x-ray-systems Accessed on 29.07.2021.

13. Malhotra A. Radiation safety and monitoring. In: Sackheim K. (eds) Pain Management and Palliative Care. Springer, New York. 2015. https://doi.org/10.1007/978-1-4939-2462-2_38.

14. Ribeiro JP. C-arm X-ray machines: All you needed to know. Orthopedics and Healthcare Technologies. 2019. Available at http://blog.peekmed.com/c-arm-x-ray-machines Accessed on 29.07.2021.

15. Mobile C-arms. Imaging Technology News. 2021. Available at https://www.itnonline.com/chart/mobile-c-arms Accessed on 29.07.2021.

16. Weinberg L, Miles LF, Allaf M et al. Video fluoroscopy for positioning of pulmonary artery catheters in patients undergoing cardiac surgery. J Cardiothorac Vasc Anesth. 2015; 6(29): 1511-1516.

17. Ujiie H, Effat A, Yasufuku K. Image-guided thoracic surgery in the hybrid operating room. J Vis Surg. 2017; 3: 148.

18. Nollert G & Wich S. Planning a cardiovascular hybrid operating room: The technical point of view. Heart Surgery Forum. 2009; 12(3): 1033.

19. Silbergleit A. 2021 C-arm prices infographic. Atlantis Worldwide. 2021. Available at https://info.atlantisworldwide.com/blog/2021-c-arm-prices-0 Accessed on 02.08.2021.

20. Jani B. Interventional mobile C-arm and angiography markets plummeted amid COVID-19. Imaging Technology News. 2021. Available at https://www.itnonline.com/article/interventional-mobile-c-arm-and-angiography-markets-plummeted-amid-covid-19 Accessed on 29.07.2021.

21. Medical Devide Authority Database. Available at https://mdar.mda.gov.my/frontend/web/index.php?r=carian Accessed on 22.10.2021.

22. Ziehm Vision Rfd Hybrid Edition. Ziehm Imaging. Available at https://www.ziehm.com/products/c-arms-with-flat-panel-detector/ziehm-vision-rfd-hybrid-edition.html Accessed on 29.07.2021.

23. Mobile C-arm fluoroscopy. Available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases Accessed on 29.07.2021.

8.0 APPENDICES

8.1 Appendix 1: Search strategy

Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to 27 July 2021

1 CARDIAC SURGICAL PROCEDURES/ (56204)
2 cardiac surgical procedure*.tw. (1180)
3 heart surgical procedure*.tw. (114)
4 THORACIC SURGERY/ (13048)
5 cardiac surger*.tw. (43162)
6 heart surger*.tw. (15842)
7 thoracic surger*.tw. (12753)
8 1 or 2 or 3 or 4 or 5 or 6 or 7 (105846)
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18 transmission computed tomograph*.tw. (135)
19 x-ray c* scan*.tw. (323)
20 x* ray computer assisted tomography.tw. (3)
21 x* ray computerized axial tomography.tw. (1)
22 x* ray compute* tomography.tw. (4059)
23 (electron beam adj2 comp* tomography).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (978)
24 IMAGING, THREE-DIMENSIONAL/ (76183)
25 3* d im ag*.tw. (1620)
26 computer-assisted three* dimensional imaging*.tw. (4)
27 compute* generated 3d imaging*.tw. (0)
28 three* dimensional imag*.tw. (6440)
29 SURGERY, COMPUTER-ASSISTED/ (18713)
30 computer* aided surger*.tw. (232)
31 computer* assisted surger*.tw. (996)
32 image* guided surger*.tw. (1138)
33 surgical navigation*.tw. (1156)
34 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 (508197)
35 ENDOVASCULAR PROCEDURES/ (21985)
36 endovascular procedure*.tw. (3356)
37 endovascular technique*.tw. (3121)
38 intravascular procedure*.tw. (85)
39 intravascular technique*.tw. (34)
40 Hybrid operation room*.tw. (30)
41 Hybrid operation room*.mp. (32)
42 Hybrid operation room*.ti. (3)
43 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 (26365)
44 IMAGE PROCESSING, COMPUTER-ASSISTED/ (130698)
45 biomedical image processing.tw. (52)
46 computer* assisted image analys*.tw. (1214)
47 computer* assisted image processing.tw. (92)
48 digital image processing.tw. (1339)

49 image reconstruction*.tw. (8060)
50 medical image processing*.tw. (505)
51 RADIOLOGY, INTERVENTIONAL/ (4308)
52 interventional radiology.tw. (6205)
53 34 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 (624953)
54 8 and 43 and 53 (49)

OTHER DATABASES	
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 1946 to July 27, 2021	Same MeSH, keywords, limits used as per MEDLINE search
Ovid MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations 1946 to July 27, 2021	
Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily 2017 to July 27, 2021	
Ovid MEDLINE(R) 1946 to July Week 3 2021	
Ovid MEDLINE(R) 1996 to July Week 3 2021	
Ovid MEDLINE(R) Epub Ahead of Print July 27, 2021	
Ovid MEDLINE(R) Daily Update July 27, 2021	
Ovid MEDLINE(R) 2017 to July Week 3 2021	
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((((((((CARDIAC SURGICAL PROCEDURES[MeSH Terms]) OR (cardiac surgical procedure[Text Word])) OR (heart surgical procedure[Text Word])) OR (THORACIC SURGERY[MeSH Terms])) OR (cardiac surgery[Text Word])) OR (heart surgery[Text Word])) OR (thoracic surgery[Text Word])) AND (((((((((((((((((((((((((((((((Ziehm Vision RFD Hybrid Edition[Text Word]) OR (FLUOROSCOPY[MeSH Terms])) OR (fluoroscopy[Text Word])) OR (TOMOGRAPHY, X-RAY COMPUTED[MeSH Terms])) OR (ct x ray[Text Word])) OR (cine ct[Text Word])) OR (electron beam computed tomography[Text Word])) OR (tomodensitometry[Text Word])) OR (transmission computed tomography[Text Word])) OR (x ray computer assisted tomography[Text Word])) OR (x ray computerized axial tomography[Text Word])) OR (x ray computed tomography[Text Word])) OR (x-ray ct scan[Text Word])) OR (IMAGING, THREE-DIMENSIONAL[MeSH Terms])) OR (3 d image[Text Word])) OR (computer-assisted three dimensional imaging[Text Word])) OR (compute generated 3d imaging[Text Word])) OR (three dimensional imaging[Text Word])) OR (SURGERY, COMPUTER-ASSISTED[MeSH Terms])) OR (computer aided surgery[Text Word])) OR (computer assisted surgery[Text Word])) OR (image guided surgery[Text Word])) OR (surgical navigation[Text Word])) OR (IMAGE PROCESSING, COMPUTER-ASSISTED[MeSH Terms])) OR (biomedical image processing[Text Word])) OR (computer assisted image analysis[Text Word])) OR (computer assisted image processing[Text Word])) OR (digital image processing[Text Word])) OR (image reconstruction[Text Word])) OR (medical image processing[Text Word])) OR (RADIOLOGY, INTERVENTIONAL[MeSH Terms])) OR (interventional radiology[Text Word]))) AND ((((((ENDOVASCULAR PROCEDURES[MeSH Terms]) OR (endovascular procedure[Text Word])) OR (endovascular technique[Text Word])) OR (intravascular procedure[Text Word])) OR (intravascular technique[Text Word])) OR (Hybrid operation room[Text Word])) Filters: Full text

8.2 Appendix 2: Hierarchy of evidence for effectiveness/ diagnostic

I Evidence obtained from at least one properly designed randomised controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

8.3 Appendix 3: Evidence tables

Evidence Table : Efficacy
Question : What is the effectiveness of a mobile C-arm fluoroscopy for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
3. Weinberg L, Miles LF, Allaf M, Pillai P, Peyton P, Doolan L. Video Fluoroscopy for Positioning of Pulmonary Artery Catheters in Patients Undergoing Cardiac Surgery. J Cardiothorac Vasc Anesth. 2015; 6(29): 1511-1516. AUSTRALIA	**Prospective, single-centre, randomised controlled trial** **Objective:** To determine whether video fluoroscopy combined with traditional pressure waveform analyses facilitates optimal pulmonary artery catheter (PAC) flotation and final positioning compared with the traditional pressure waveform flotation technique alone. **Method:** The trial was carried out between July 2010 and July 2012 at a university teaching hospital with complex cardiac surgery experiences. Inclusion criteria: Adult patients considered to be at higher risk for difficult pulmonary artery catheter insertion who were undergoing elective	I	50 patients: 25 in fluoroscopy group, 25 in usual-care group	Video fluoroscopy combined with pressure waveform monitoring	Pressure waveform monitoring alone		Mean (SD) time to float the pulmonary artery catheter was significantly shorter in the fluoroscopy group: 73s (SD 65.1) vs 176s (SD 180.6) in the usual-care group; p=0.014. The median (IQR) number of attempts to successful floatation was lower in the fluoroscopy group: 1(IQR 1:2) attempts vs 2 (IQR 1:4) attempts in the usual-care group; p=0.007. No significant difference in the number of patients who experienced an arrhythmia during pulmonary artery catheter insertion (8 patients in the usual-care group vs 4 patients in the fluoroscopy group; p=0.32). Author's conclusion: In patients considered at higher risk for pulmonary artery catheter-related complications who were undergoing cardiac surgery, video fluoroscopy facilitated faster and safer pulmonary artery catheter floatation and positioning compared with the traditional pressure waveform floatation technique alone.	

Evidence Table : **Efficacy**
Question : **What is the effectiveness of a mobile C-arm fluoroscopy for Cardiothoracic Surgery?**

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	or semi-urgent cardiac surgery that necessitated a pulmonary artery catheter as part of routine perioperative care. Criteria for inclusion were obtained from routine preoperative transthoracic or transesophageal echocardiography, coronary angiography and right heart catheterisation studies. Exclusion criteria: Age below than 18 years old, no ability to provide informed and written consent (eg: patient awaiting surgery in the intensive care unit who had been administered sedatives), and time-critical surgery in which induction of anesthesia was imperative before the pulmonary artery catheter being inserted. Patients were assigned randomly into two groups using a computer-generated program: those in whom the pulmonary artery catheter was floated							

Evidence Table : Efficacy
Question : What is the effectiveness of a mobile C-arm fluoroscopy for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	using video fluoroscopy combined with real-time pressure waveform monitoring (fluoroscopy group), and those in whom the pulmonary artery catheter was floated by real-time pressure waveform monitoring along (usual-care group). Cardiac output measurements were performed via a right heart catheter study in six patients during preoperative cardiac catheterisation. The pulmonary artery catheter was inserted via the right internal jugular vein of all patients.							

Evidence Table : Efficacy
Question : What is the effectiveness of a mobile C-arm fluoroscopy for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
1. Ujiie H, Effat A, Yasufuku K. Image-guided Thoracic Surgery in the Hybrid Operation Room. J Vis Surg. 2017; 3(148). CANADA	**Case Study** **Objective:** To describe the capabilities of the guided therapeutics system, the first-in-human technologies used and evaluated in guided therapeutics operating room. **Method:** A hybrid operating room was developed to establish the efficacy of different minimally invasive therapies, known as the guided therapeutics operating room at the Toronto General Hospital. The guided therapeutics operating room was equipped with multi-modality image-guidance systems, which featured a dual source-dual energy computed tomography (CT) scanner, a robotic conebeam CT (CBCT)/ fluoroscopy, high-performance endobronchial ultrasound	III	-	Multi-modality image-guidance systems: fluoroscopy			X-ray fluoroscopy was used to confirm the location of the microcoil to carry out the video assisted thoracoscopic surgery (VATS). The use of the guided therapeutics operating room allowed the ability to perform a series of surgical procedures without the need to transfer the patient to any other room, ultimately supporting improved workflow throughout the procedure.	

Evidence Table : Efficacy
Question : What is the effectiveness of a mobile C-arm fluoroscopy for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	system, endoscopic surgery system, near-infrared (NIR) fluorescence imaging system, and navigation tracking systems.							

Evidence Table : Efficacy
Question : What is the effectiveness of a mobile C-arm fluoroscopy for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
2. Nollert G, Wich S. Planning a Cardiovascular Hybrid Operating Room: The Technical Point of View. The Heart Surgery Forum. 2009; 12(3):1033. GERMAN	**Pilot Study** **Objective:** To study the integration of interventional techniques into cardiovascular surgery which requires angiographic imaging capabilities in an operating room. **Method:** Not stated.		-	Intraoperative 3D imaging with angiography system combined with fluoroscopy.			Fluoroscopy required a smaller radiation dose, brilliant fluoroscopy images were the predominantly used images during surgery; however, modern angiography systems offered advanced imaging and post-processing capabilities including image fusion with any type of previously acquired 3D volumes, guidance, or 3D imaging.	

Evidence Table : Safety
Question : Is mobile C-arm fluoroscopy safe for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
3. Weinberg L, Miles LF, Allaf M, Pillai P, Peyton P, Doolan L. Video Fluoroscopy for Positioning of Pulmonary Artery Catheters in Patients Undergoing Cardiac Surgery. J Cardiothorac Vasc Anesth. 2015; 6(29): 1511-1516. AUSTRALIA	**Prospective, single-centre, randomised controlled trial** **Objective:** To determine whether video fluoroscopy combined with traditional pressure waveform analyses facilitates optimal pulmonary artery catheter (PAC) flotation and final positioning compared with the traditional pressure waveform flotation technique alone. **Method:** The trial was carried out between July 2010 and July 2012 at a university teaching hospital with complex cardiac surgery experiences. Inclusion criteria: Adult patients considered to be at higher risk for difficult pulmonary artery catheter insertion who were undergoing elective or semi-urgent cardiac surgery that necessitated a pulmonary artery	I	50 patients: 25 in fluoroscopy group, 25 in usual-care group	Video fluoroscopy combined with pressure waveform monitoring	Pressure waveform monitoring alone		The composite complication rate (malposition and arrhythmias) was greater in the usual-care group than in the fluoroscopy group (52% vs 16%, respectively); p=0.01).	

Evidence Table : Safety
Question : Is mobile C-arm fluoroscopy safe for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	catheter as part of routine perioperative care. Criteria for inclusion were obtained from routine preoperative transthoracic or transesophageal echocardiography, coronary angiography and right heart catheterisation studies. Exclusion criteria: Age below than 18 years old, no ability to provide informed and written consent (eg: patient awaiting surgery in the intensive care unit who had been administered sedatives), and time-critical surgery in which induction of anesthesia was imperative before the pulmonary artery catheter being inserted. Patients were assigned randomly into two groups using a computer-generated program: those in whom the pulmonary artery catheter was floated using video fluoroscopy combined with real-time pressure waveform							

Evidence Table : Safety
Question : Is mobile C-arm fluoroscopy safe for Cardiothoracic Surgery?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	monitoring (fluoroscopy group), and those in whom the pulmonary artery catheter was floated by real-time pressure waveform monitoring along (usual-care group). Cardiac output measurements were performed via a right heart catheter study in six patients during preoperative cardiac catheterisation. The pulmonary artery catheter was inserted via the right internal jugular vein of all patients.							

e ISBN 978-967-2887-24-9