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Implementation trial of a coaching intervention to increase the use of a recommended technique for coronary heart surgery (transradial percutaneous coronary interventions)

Submission date
05/05/2020

Recruitment status
No longer recruiting

Registration date
07/12/2020

Overall study status
Completed

Last Edited
11/02/2022

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to test the effectiveness of a coaching intervention to promote greater use of the transradial approach for cardiac catheterizations (TRA). Previous research has demonstrated that TRA is safer, more comfortable for patients and less costly than the transfemoral approach which is the dominant approach in U.S. cath labs, with TRA accounting for just over 20% of PCIs in the U.S.
The issue does not appear to be lack of awareness about the advantages of the procedure, rather most cardiologists in US fellowships are trained to perform caths via the femoral artery, and there are few training opportunities for operators to learn to perform TRA after fellowship. There is a well-documented learning curve of between 30 and 50 cases before cardiologists become proficient performing caths via the radial artery; during the learning curve they perform caths more slowly and have a higher crossover rate, i.e., are sometimes unable to complete the procedure via the radial artery and switch to the femoral route. The primary challenge appears to be getting cardiologists through this learning curve.
We hypothesize that coaching by an experienced cardiologist and cath lab nurse can help new radial operators and their teams overcome the learning curve. Based on our successful pilot study conducted in 2012 and 2013, this study aims to determine the effectiveness, safety and cost-effectiveness of a comprehensive coaching program. Ultimately, we hope this coaching intervention will help increase the use of TRA in VA cardiac catheterization laboratories and can be a model for helping speed the adoption of other complex procedures that cardiologists try to adopt after completing fellowship.

Who can participate?
The participants are VA cardiologists, cath lab nurses and cath lab technicians. Six to nine VA cardiac catheterization laboratory sites (i.e., cath labs) will be recruited to participate. The goal is to include two to three staff members per cath lab site: at least one interventional or invasive

cardiologist, and a cath lab nurse and/or a cath lab technician. Participation in this study is voluntary.

What does the study involve?
The study intervention comprises two activities: (1) a one-day, team-based, in-person training at an experienced cath lab; and (2) a one-day visit by an experienced cardiologist coach and cath lab nurse coach.
The day-long, team-based training program is held at the Jesse Brown VA Medical Center in Chicago, IL, or the Durham VA Medical Center in Durham, NC. Participating cath lab teams will be randomized to one of three training cohorts, and participating members of a given lab will attend together. This program will include education on safety procedures and the benefits of transradial over transfemoral cardiac catheterizations. Then, participants will view live cases performed by an experienced team.
Approximately one month after the in-person training, participating sites will host a coaching visit by an experienced TRA interventionalist and cath-lab nurse. The participating team schedules two to four cases to be performed via TRA. The cath lab nurse coach reviews pre-procedure preparation and post-procedure care with the participants. The coaches observe the cases, and are available to provide input in real time and feedback after each case. The coaches focus on providing feedback about lessons learned to help participating teams overcome common obstacles to performing TRA efficiently and well. The coaches are also available to answer questions from non-study participants in the cath lab and provide encouragement.
In addition to the study intervention, participants are interviewed and complete surveys.
There are three interviews: one pre-training, and two post-training (approximately 6 months apart). Questions include perceptions of and barriers to TRA at the participants' facilities, and input on topics the participant would like addressed at the team-based training. The interviews are conducted by phone and take about 40 minutes.
There are three surveys: one pre-training and two post-training (approximately 6 months apart). Surveys assess perceptions of and barriers to TRA at the participants' facilities, prior TRA training, organizational readiness to change and demographic information. Surveys are conducted online and take approximately 15 minutes.

Where is the study run from?
The study is run from the United States Department of Veterans Affairs, Puget Sound Health Services Research & Development, Seattle, WA.

When is the study starting and how long is it expected to run for?
January 2017 to January 2021

Who is funding the study?
US Department of Veterans Affairs Health Services Research & Development (HSR&D) (USA)

Who is the main contact?
If you have any questions, comments or concerns about the research, please contact the study team at pugtrastudy@va.gov

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
VA IIR 15-362

Study information

Scientific Title
Implementation trial of a coaching intervention to increase the use of transradial percutaneous coronary interventions

Study objectives

A coaching intervention led by an experienced cardiac cath cardiologist and nurse will increase use of the trans-radial approach among participating cath lab teams

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/08/2014, VA Central Institutional Review Board (810 Vermont Avenue, NW Washington DC 2042, USA; +1 202-443-5766; Kendra.Clarke2@va.gov), ref: none provided

Study design
Stepped-wedge type 3 hybrid implementation trial

Primary study design
Interventional

Secondary study design
Randomized stepped-wedge

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Percutaneous coronary interventions via the radial artery (trans-radial approach or TRA) or the femoral artery (trans-femoral approach or TFA)

Interventions
Once enrolled in the study, participating cath lab teams are randomized to one of three intervention cohorts, with each cohort including up to three sites. The Participating cath lab teams, which comprise an invasive or interventional cardiologist with a cath lab nurse and/or cath lab technician from their site, ants are notified by email of their study cohort site assignment, and are invited by email to complete an online survey that assesses their perceptions of TRA, and contextual factors such as workplace climate. Participants also receive information about arranging official travel in VA, which is necessary for them to complete the first component of the intervention (travel to an in-person radial training session).

Each of the three cohorts receives the coaching intervention approximately four-months apart. The coaching intervention consists of the participants attending the in-person, one-day radial training session held in Chicago or Durham, and hosting the one-day visit by a coaching team to the participants' sites. The coaching visit occurs approximately one-to-two months after the in-person training. Participants are also asked to complete phone interviews and online surveys following the conclusion of the coaching visit, and again six months later.

The research team assists participants with travel to the in-person training, and with scheduling the coaching visit. The research team also contacts the participating sites' facility leadership (e.

g., medical center director, chief of staff) via email to alert them to the members' of the cath lab participation in the study, in order to ensure the leadership is aware of the upcoming visit to their facility by the coaches.

All participants receive contact information for the clinical coaching and research team and are encouraged to contact the coaching team if they have questions or need assistance as they work to increase their use of TRA. Any contacts that coaches receive from participating sites are documented during routinely-scheduled calls that the research team conducts with coaches.

Other study data, e.g., the primary outcome of rate of TRA use, are collected through an existing VA cardiac cath lab registry, the Clinical Assessment Reporting and Tracking -Cath Lab (CART-CL) system, which includes standard data elements developed for the American College of Cardiology National Cardiovascular Disease Registry. The research team obtains patient-level CART-CL data for all VA cath labs, including participating sites, to include a period of at least or all participating sites, August 1, 2017 to July 31, 2020.

To randomize sites, we used Random.org to generate a random sequence of 9 integers, 1 to 9 (IP: 174.21.137.15, Timestamp: 2018-04-10 06:15:01 UTC), and applied it to the alphabetical list of enrolled sites. Sites assigned 1 to 3 were cohort 1; 4 to 6 were cohort 2; and 7 to 9 were cohort 3.

Note on changes from original study plan: After enrollment and randomization, we had a number of changes that violated study randomization. First, due to administrative delays in sites receiving travel authorization, the scheduled training for cohort two had to be cancelled and rescheduled, resulting in cohort two receiving the intervention out of sequence. Second, three sites withdrew prior to receiving the coaching intervention; the reasons for withdrawal were site-specific events, such as departure of cath lab personnel. Third, we enrolled two additional sites after initial study randomization, assigning them to intervention cohort based on their availability to travel: one of the two withdrew prior to receiving the study intervention, and the other received the intervention. In total, 11 sites enrolled with 7 receiving the intervention and 4 withdrawing prior to receiving the intervention. We will report the original study enrollment and randomization, and all withdrawals, deviations and additions in a planned main findings paper. The main findings paper will report primary findings performed as intent-to-treat of sites as randomized, with secondary analyses performed as-treated of all participating sites. The intent-to-treat analysis will be possible because TRA rates are available for all VA cath labs through the CART-CL registry.

Intervention Type
Behavioural

Primary outcome measure
The proportion of cardiac catheterizations accessed through the radial artery (TRA catheterization) performed at the VA hospital 12 months pre-intervention and 12 months post-intervention assessed using patient records

Secondary outcome measures
1. Bleeding complications during surgeries measured using patient records
2. Employee job satisfaction measured using a two-item self-report measured at baseline, immediately following the coaching visit, and at 6 months follow up
3. Organizational commitment measured using a single item self-report measured at baseline, immediately following the coaching visit, and at 6 months follow up

Overall study start date
01/01/2012

Completion date
07/01/2021

Eligibility

Key inclusion criteria
VA employees working in a VA cardiac catheterization laboratory as either an invasive or interventional cardiologist, nurse, or technician.

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Up to 9 VA cardiac cath labs and up to 27 participants (3 per cath lab)

Key exclusion criteria
Sites will be excluded if:
1. One of the study coaches is located at the site
2. The site previously participated in our pilot study
3. They perform fewer than 100 catheterizations per year
4. They have current radial rates of greater than 50% for either PCI or diagnostic catheterization

Date of first enrolment
09/01/2017

Date of final enrolment
04/01/2019

Locations

Countries of recruitment
United States of America

Study participating centre
VA Puget Sound Healthcare System
1660 S. Columbian Way, S-152
Seattle
United States of America
98108

Study participating centre
Durham VA Health Care System
508 Fulton Street
Durham
United States of America
27705

Study participating centre
Jesse Brown VA Medical Center
820 S Damen Ave
Chicago
United States of America
60612

Study participating centre
VA Eastern Colorado Health Care System (Denver)
13701 E Mississippi Ave
Aurora
United States of America
80012

Study participating centre
VA Long Beach Healthcare System
5901 East 7th Street
Long Beach
United States of America
90822

Study participating centre
Overton Brooks VA Medical Center
510 E Stoner Ave
Shreveport
United States of America
71101

Study participating centre
Wilkes-Barre VA Medical Center
1111 East End Blvd

Wilkes-Barre
United States of America
18711

Sponsor information

Organisation
Health Services Research & Development

Sponsor details
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Sponsor type
Government

Website
https://www.hsrd.research.va.gov/

ROR
https://ror.org/0083hz885

Funder(s)

Funder type
Government

Funder Name
Health Services Research and Development

Alternative Name(s)
VA Health Services Research and Development Service, VA HSR&D, Veterans Health Administration HSR and D, HSR&D

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United States of America

Results and Publications

Publication and dissemination plan
In addition to standard dissemination (presentation of results at national meetings; publications), we will present the results to key operational aspects of VA, including the National Leadership Board and members of Patient Care Services.

Intention to publish date
07/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the research authorization the study operates under does not permit release of CART-CL data beyond reporting study findings, including release of de-identified datasets. CART-CL data are available through requests directly to CART-CL: https://www.va.gov/healthcareexcellence/cart/index.asp

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1.8	29/01/2020	04/01/2021	No	Yes
Other publications	Cost analysis	27/10/2021	11/02/2022	Yes	No
Protocol article	Design and baseline results	25/10/2021	11/02/2022	Yes	No