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MINIREVIEWS

Cardiac arrest and cardiopulmonary resuscitation in "hostile" environments: Using automated compression devices to minimize the rescuers' danger

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Abstract

Mechanical automated compression devices are being used in cardiopulmonary resuscitation instead of manual, "hands-on", rescuer-delivered chest compressions. The -theoretical- advantages include high-quality non-stop compressions, thus freeing the rescuer performing the compressions and additionally the ability of the rescuer to stand reasonably away from a potentially "hazardous" victim, or from hazardous and/or difficult resuscitation conditions. Such circumstances involve cardiopulmonary resuscitation (CPR) in the Cardiac Catheterization Laboratory, especially directly under the fluoroscopy panel, where radiation is well known to cause detrimental effects to the rescuer, and CPR during/after land or air transportation of cardiac arrest victims. Lastly, CPR in a coronavirus disease 2019 patient/ward, where the danger of contamination and further serious illness of the health provider is very existent. The scope of this review is to review and present literature and current guidelines regarding the use of mechanical compressions in these "hostile" and dangerous settings, while comparing them to manual compressions.

Key Words: Automated compression devices; Cardiopulmonary resuscitation; Cathlab; Computed tomography; Transfer; COVID-19

Core Tip: The use of automated compression devices in 'hostile' environments, both in in- and out-of-hospital cases of cardiac arrest, seems to be beneficial both regarding compressions' quality but especially the rescuers' safety. So far, while experimental data is extensive, real-life studies examining their use in non-friendly situations are still limited. Since high-quality cardiopulmonary resuscitation remains the key to a successful resuscitation, their use such difficult and "hostile" situations should be seriously taken into consideration. Noteworthy, such a use is indeed implied by guidelines.

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INTRODUCTION

Cardiopulmonary resuscitation (CPR) is the pillar of cardiac arrest treatment. High numbers of people sustain cardiac arrest both inside and outside of the hospital every year[1] thus, making the need for high-quality CPR crucial, in order to save human lives.

The cornerstone of high-quality CPR is effective chest compressions (CC). The characteristics of great-quality CCs are proper rate, adequate depth, full chest recoil, and minimal interruptions[2]. However, during the highly demanding resuscitation setting optimal quality of CCs is not always achieved. Rescuer exhaustion is the main reason for suboptimal CCs, as compressions are extremely demanding and tiring for the providing rescuer. In a study of manual compressions, the vast majority of rescuers reported serious back discomfort, mostly related to the duration of CPR, while approximately 20% of the rescuers suffered back injury or reported a prolapsed-disk diagnosis[3].

Besides operator exhaustion, hostile settings related to cardiac arrest are often the reason for CCs of suboptimal quality. Those settings include but are not limited to, resuscitation in a moving ambulance during patient transportation, inside the computed tomography (CT) scanner, or in the cardiac Catheterization Laboratory (CathLab). Especially for the CathLab, it is not only difficult for the operator to perform high-quality CCs due to the existence of the equipment, but it is also very dangerous, due to the hazardous ionizing radiation.

Mechanical automated chest compression devices (ACDs) implement all the necessary qualifications to solve all the aforementioned problems and have been implemented in clinical practice. Many studies, reviews, and meta-analyses have contemplated the use of ACDs in the clinical setting of a cardiac arrest, presenting both the upsides of their use and the potential obstacles. ACDs can deliver high-quality compressions, of consistent rate and depth, lasting up to one hour when disconnected from their energy source[4,5].

There are mainly two device types of ACDs, based on the compressions' delivery style (Figure 1). The first type is piston-driven (PD) (Lucas© Stryker Medical, United States, Life-Stat© Michigan Instruments, United States) –thus applying anteroposterior thrust on the sternum. A recent study showed that the use of a piston-driven ACD (which uses a suction cup) is associated with higher coronary perfusion pressure[6]. The second type of ACD uses a load-distribution band (LDB) (Autopulse© Zoll Medical Corp, United States) and distributes the force applied to the patients' torso more evenly[7]. Both types have been studied in the settings of both the in-hospital cardiac arrest (IHCA) and the out-of-hospital-cardiac arrest (OHCA) and they seem to be more beneficial in the setting of IHCA[7]. A novel idea, however, is that they can be of great value in a 'non-friendly' setting of a cardiac arrest, either IHCA or OHCA. In this review, we present current data and literature regarding the implementation of ACDs in cardiac arrest in a 'hostile' environment.

IN-HOSPITAL CARDIAC ARREST

The use of ACDs in the hospital environment (Figure 1) combines various advantages. The devices can be deployed fast, and they solve the problem of energy loss, as the in-hospital hospital-bed mattresses tend to absorb up to 40% of the force produced during chest compressions[8]. They are easier to use and considerably less invasive than the Extracorporeal Membrane Oxygenation that is used in cardiac arrest settings, and they additionally require easier training[9]. Furthermore, the infrastructure of the hospital environment is highly advanced, offering high-quality post-resuscitation care, a well-trained resuscitation team, very efficient airway management, and minimized response times; thus, in-hospital setting CPR, assisted by ACDs, can offer a superior, more organized peri-arrest care to patients. So far, data indicated that the use of ACDs in the IHCA setting can be beneficial when compared to manual cardiac compressions, although further data could elucidate more on the standing debate[7].

However, although the ACDs can offer a sustainable solution to the very important constant-high-quality-compressions problem, they can pose limitations. Patient safety has been studied, and patient injuries (such as rib fractures, liver lacerations, or vertebral body fractures) have sporadically been reported[9]. Furthermore, device failure has also been reported[10,11]. A learning curve required for the correct use and placement of the devices, with minimum interruptions of the ongoing manual compressions, has also been brought to attention[10]. The randomized COMPRESS-RCT study[12], although prematurely terminated due to unfavorable outcomes in the use of a certain ACD type (Lucas) in the hospital environment, did accentuate important aspects and limitations regarding the implementation of efficient ACD-study protocols. Hospital survival was low, while the identified problems where delays in the intra-arrest randomization, non-superior compressions quality in the Lucas arm, and low overall recruitment[12].

In-hospital 'hostile' environment

Radiation exposure: Despite the limitations arising from using ACDs in the hospital environment, data suggest that their use in special settings and non-friendly situations is beneficial and even suggested. More specifically, although improved techniques, equipment, and training led to a fall in cardiac arrest cases in the cardiac cath lab[13], prolonged CPR may still be required[13]. The presence of the equipment as well as the ionizing radiation constitute a 'hostile' environment. Radiation exposure during manual CCs is a major concern, as accumulated doses over time have been associated with multiple health hazards[14]. As a result, the protection of the rescuers from radiation should be a priority. The use of ACDs in the CathLab can substitute manual compressions, thus eliminating the need for extra personnel during the resuscitation process. Furthermore, ACDs can offer good-quality compressions during the ongoing catheterization process (*i.e.* primary PCI), as they are greatly translucent[15]. The Lucas device has been reported to allow free movement of the radiation detector and allow all views during catheterization, except for the straight anteroposterior[16]. The device compressions do not affect the interventions during catheterization, although minor interruptions for coronary stenting may be warranted[16]. Although the initial device deployment delay has been reported as a drawback, the time needed can be reduced to a median of seven seconds with proper staff training[17]. So far, the Lucas device has been mainly studied in the CathLab in the form of case reports. During PCI arrest, it has been shown that the device, when compared to manual CCs, has better outcomes in terms of both return of spontaneous circulation (ROSC) and survival rates at hospital discharge[18]. The blood pressure levels that the device can maintain during resuscitation are also of vital importance[19]. The device can also assist the resuscitation process as it can be used during the transportation of the patient to the cath lab. A study contemplated that better ROSC rates are achieved for patients transferred to the CathLab with ongoing mechanical compressions[20]. In the event of PCI, a Lucas case series argued that the device was beneficial for patients[16]; Autopulse case reports also argue that uninterrupted visualization during catheterization is achieved thus allowing all interventions [21,22]. On the other hand, a study stated that ongoing CPR upon arrival at the CathLab and continuous mechanical compressions for over 10-20 min in the CathLab were both predictive of poor outcomes[23]. Of interest, a recent study revealed that for patients undergoing PCI under mechanical compressions,

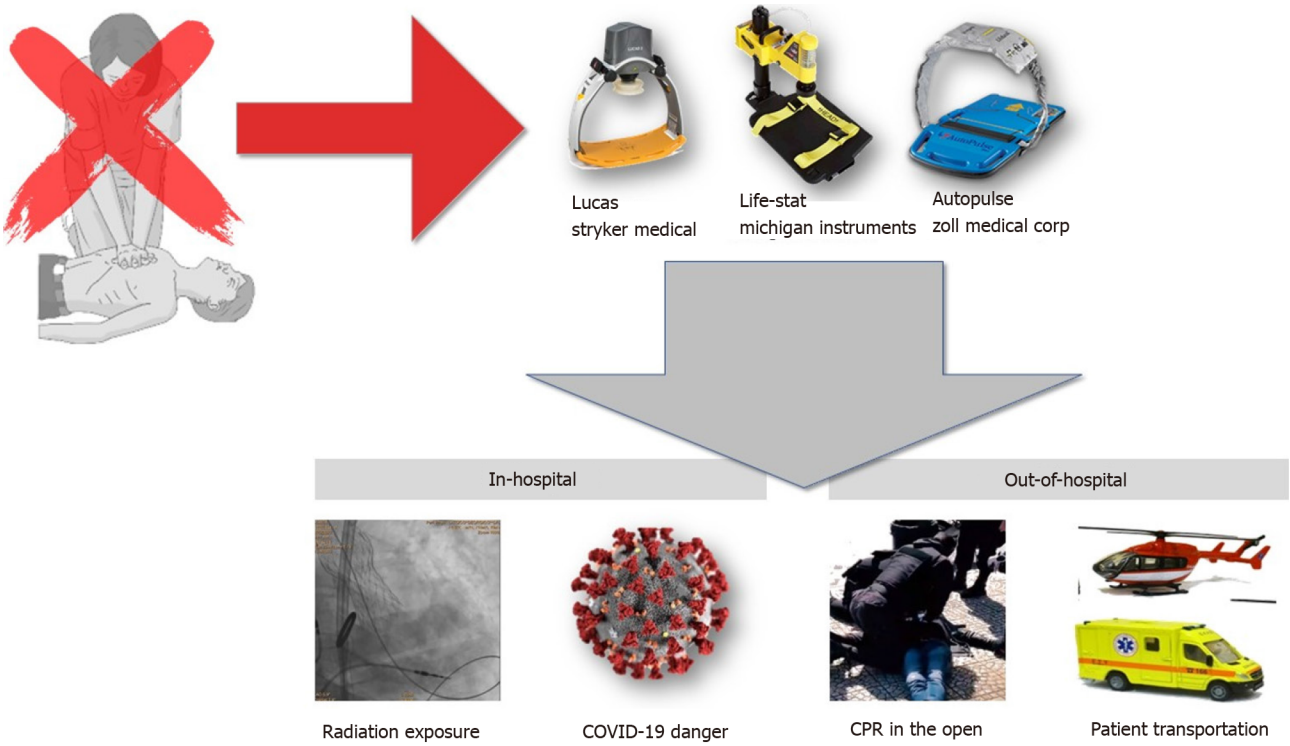

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Figure 1 Automated compression devices instead of hands-on manual cardiopulmonary resuscitation to minimize the rescuers' danger in in-hospital and out-of-hospital cardiac arrest resuscitation. COVID-19: Coronavirus disease 2019; CPR: Cardiopulmonary resuscitation.

mild hyperkalemia might be beneficial, identifying the potassium (KCl) concentration of 5.1 mmol/L to be the optimal cut-off, for the prediction of survival to hospital discharge[24].

The topic of ACD compressions inside the CT scanner has not been studied as extensively. So far, a case report of a pulmonary embolism that sustained cardiac arrest suggested that contrast-enhanced CT imaging with ongoing chest compressions is feasible after cardiac arrest[25]. Experimental data suggest that an ECG-triggered protocol allows almost artifact-free chest evaluation during mechanical compressions[26].

Coronavirus disease 2019 danger: CPR is a complex intervention, requiring extensive skills from quite a few knowledgeable healthcare providers. The risks of viral transmission through aerosol and droplet generation during CPR have not yet been fully identified, but a transmission can be detrimental to these valuable and scarce CPR team members[33]. On the other hand, patients with coronavirus disease 2019 (COVID-19) who require intubation and ventilation have extremely poor survival rates[27-29]. The best way to express this concept has already been written, and we also stand for[30]: This pandemic has changed the risk-benefit balance for CPR: from "there is no harm in trying" to "there is little benefit to the patient and potentially significant harm to staff".

During the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus pandemic, the advanced life support algorithm must be followed with extreme caution to personal protection, especially regarding personal protective equipment, airway management, and compressions, and an ACD should be used, as soon as the device is available[31-32]. The high contagiousness of the SARS-CoV-2 virus changed significantly every day clinical practice and the CPR process. Occupational exposure of healthcare and other personnel to all airborne transmitted pathogens is not by any means negligible but can be minimized through a high index of suspicion, preparedness, and appropriate protection[33].

Regarding changes and additions to the already existing OHCA protocol, it is suggested that cardic arrest recognition should be performed by searching for the absence of pulse and normal breathing while completely avoiding listening to or feeling breath sounds, by placing one's ear and cheek near the victim's mouth[31]. A cloth should also be placed on the unconscious victim's mouth during the resuscitation process. CPR should be performed only through chest compressions and quick and effective use of an AED is of vital importance without any additive risk to the resuscitation process. Hand sanitizing is an efficient alternative to soap-based hand washing, which is advised immediately after the process[31,34].

Regarding the IHCA CPR process, advanced airway management is mainly endotracheal intubation should be performed by the most trained and experienced physician, as the risk of cross-infection is high. The use of PPE is highly advised in the hospital setting, while participants in the CPR process

should be trained on how to correctly handle, put on and safely remove all PPE equipment[31,34]. As the need for protection through PPE use may delay CPR initiation for patients with COVID-19, "donning/doffing" training can help minimize those delays. Regarding the algorithm, adjustments have been made to accommodate those newly surfaced needs; no CPR should commence without the use of PPE, and for shockable rhythms, up to three back-to-back shocks are allowed to restore the patient's rhythm. CPR should start only with chest compressions, while defibrillation for all shockable rhythms should be given with only minimal delays[31,32].

A mechanical compression device should be used as soon as it becomes available in any setting that allows their safe and efficient use, especially in the need for prolonged CPR[7,34]. The obvious advantage, besides the ones already discussed earlier, is the need for one less –COVID-19 exposed-person in the CPR team. Furthermore, this at-risk person would be the one the closest for the longest duration, to the SARS-CoV-2 infected victim. Therefore, automated chest compression devices have been proposed to be used during COVID-19 CPR[35,36]. When they are not available it was discussed to reduce the duration of the CPR cycles from two to one minute as the quality of chest compressions can deteriorate fast if the rescuer wears PPE[33,35,36].

OUT-OF-HOSPITAL CARDIAC ARREST

The ACDs have been studied quite extensively in the setting of an OHCA (Figure). So far the results are mixed, as a study suggested that a load distribution band presents worse neurological outcomes and worse survival when compared to manual CCs; however, a meta-analysis concluded that ACDs are associated with better ROSC outcomes, provided that the staff applying them is sufficiently trained[37,38]. In the same meta-analysis, load-distribution devices outperformed piston-driven devices, a finding that may be associated with the necessary pause for application[38,39]. Interestingly, in another meta-analysis of survival to thirty days, it was found that survival to hospital admission or survival to discharge was comparable between the two arms (manual CCs and the Lucas device), although manual CPR proved superior to the Autopulse device; regarding patient safety, manual CCs were superior to the devices[7,40].

Out-of-hospital 'hostile' environment

The OHCA setting is at its core the most challenging one. Compressions, of undetermined quality, are most often initiated by bystanders after significant delays. ADCs, brought by the rapid response EMS (emergency medical system *e.g.* ambulances or motorcycles) can offer continuous high-quality compressions, on the scene of a cardiac arrest, while defibrillation can take place simultaneously; in this way, quality is maintained at a high standard and the need for pauses is minimized[38]. However, in the randomized ASPIRE trial the deployment of the load-distribution device created a delay of 2.1 min to the first shock in ventricular fibrillation. As a result, the trial was prematurely terminated due to neurological and survival adverse outcomes[37]. In another randomized trial no difference regarding early survival between the manual and the mechanical arm was noted[41]. Prolongation of time to first shock was also prominent in CIRC and LINC trials[42,43]. Applicability factors, such as body weight, have also been highlighted and they may also cause delays[42,43]. In a recent study, the mechanical (Lucas) arm did not show added benefit regarding the ROSC rate, but its use did not lead to a higher risk of traumatic injury. The same study suggested that ACDs may be more useful in cases of delayed ambulance response times, or events happening in remote locations[44]. However, liver lacerations, occasionally associated with massive post-resuscitation hemorrhage, have been twice reported in the Lucas arm along with one Autopulse-associated tension pneumothorax that caused an air embolus[45]. The pre-hospital use of ACDs has been associated with worse neurological outcomes to hospital discharge when compared to manual compressions[46,47]. The LINC trial randomized SCA victims into manual compression *vs* Lucas-mediated compressions on the scene and showed no differences in either four-hour survival, six-month survival, or neurological outcomes between the two arms[43]. Similarly, in the PARAMEDIC trial (2:1 randomized trial of manual CCs: Lucas) no superiority of the device was proven in the primary outcome of thirty-day survival[48]. Furthermore, in the randomized CIRC trial (LDB device *vs* manual CPR) the two arms of the study displayed similar survival rates and neurological outcomes to discharge[42]. However, ACDs have been proposed to improve both pre-hospital and admission-to-hospital survival, especially when operated by a two-member paramedic team, the victim is young and the arrest takes place in a city center[5,7].

Cardiac arrests that are treated within Emergency Departments are considered cases of OHCA[49]. Patients that are treated for cardiac arrest in the Emergency Department are in the vast majority, patients that sustained a cardiac arrest outside of the hospital and were transferred with continuous compressions to the ED; thus, the resuscitation process can be quite challenging and may pose difficulties. Research has not definitively concluded regarding the effect of ACDs in ED departments. While a large randomized trial from Japan concluded that the mechanical arm of patients treated in the ED for an OHCA presented worse survival outcomes possibly due to deployment pauses[50], another randomized trial examined the effect of trained personnel operating LDB devices and concluded that

better CPR quality is delivered to the patient, with shorter interruption times during deployment of the device[51].

However, the most challenging setting is during patient transportation. Cardiac arrest patients are sometimes transferred to the hospital with ongoing CPR, of doubtful quality[52] or they may arrest en route to the hospital. Rather conclusive data showed manual compressions during transfer to be ineffective for the patient and unsafe for the providing staff[53]. Various difficulties -including but not limited to uneven pavements and tight spaces and doorways during the victim transfer to the ambulance, sudden stops, accelerations, turns, and confined ambulance space, adversely affect delivered CPR quality[7]. Those are the exact settings in that an ACD may effectively assist the resuscitation process and favorably alter its course. An observational study found that ACDs use, contrary to manual CPR, minimizes compression interruptions during the extrication of a patient, except for the deployment pause[54]. Research has presented beneficial outcomes so far for the use of ACDs of both types during transportation, in terms of higher ROSC, survival to hospital admission, and quantitative CPR quality irrespective of transportation conditions or vehicle type[55,56]. However, regarding survival and outcomes, the heterogeneity of the included trials still poses a significant challenge to the generalization of the results. In every case, the vast majority of studies highlight the need for proper personnel training. The Danish cardiac arrest registry reported a marked reduction in mortality, when resuscitated OHCA victims were transferred to CathLab-capable tertiary centers rather than when being transferred to the nearest district hospital, irrespective of the overall distance the resuscitated victim had to travel by ambulance[57]. During the resuscitation process, an OHCA victim may need to undergo a large distance transportation by ambulance. ACDs may facilitate the process, thus having a place in the resuscitation process during transportation. Experimental data, using manikins, has concluded that the Lucas-2 device, in use by experienced hands, is a good alternative to manual compressions during a rescue-helicopter transfer and it complies -as a system- with all European Resuscitation Council (ERC) recommendations[58]. A randomized study, also using manikins, concluded that the Lucas system increased CPR quality and reduced pauses during helicopter rescue, but prolonged the time interval to first defibrillation[59]. Similarly, regarding transportation down stairwells and through tight spaces, experimental data proposing a new Lucas-2 system with shoulder strap fixation during non-supine stretcher transportation, allowed uninterrupted compressions, while yielding better chest compression fractions for the overall resuscitation period[60]. A randomized triple cross-over experimental study in an alpine setting revealed that Corpuls and Lucas-3 maintained the adequate quality of CPR during transportation and the piston was placed correctly even during challenging terrestrial transport[61]. Furthermore, a manikin-based study contemplated that while ambulance speed can affect manual compressions quality during transportation, devices of both types can resolve quality issues[62]. A similar experimental study showed good device performance during transport on a soft stretcher or gurney involving a stairwell, trips with a turntable ladder, a rescue basket, and an ambulance including loading/unloading of the patient, but underlined the need to check patient-device connection and stability[63]. All experimental studies highlight the need for real-world data. A retrospective observational study in Switzerland concluded that the implementation of mechanical compression devices in helicopter transportation can be beneficial, especially for non-trauma patients[64]. However, a recent German registry reported that mechanical devices are not associated with better survival rates when used during transport, but are associated with better survival in prolonged resuscitation. They are, however, associated with worse survival when a fibrinolytic was used; rescuer safety could be a sufficient reason for their use[65].

The use of mechanical compression devices has been used as a bridge to uncontrolled organ donation [66]. Although both ethical and clinical challenges are raised, the use of ACDs can reduce the time of warm ischemia[67]. During the insertion of extracorporeal CPR (cardiopulmonary bypass), the use of an ACD may be useful and it is applied with positive results, although data are still scarce[7]. In the case of refractory cardiac arrest, ethical dilemmas require very careful consideration[68].

GUIDELINES

Regarding current guidelines for in-hospital practice, the American Heart Association in 2010 stated that piston-driven or load-distributing band chest compression devices may be considered in patients undergoing PCI or CT scanning, for prolonged resuscitation (class IIa) or when manual resuscitation is challenging (class IIb)[69].

The ERC in its 2015 guidelines strongly recommended the use of ACDs in the cath lab during coronary interventions[70]. It is mandatory for trained personnel to implement the use of such devices, but there is insufficient evidence to support or refute their routine use in cardiac arrest[7].

In the latest (post COVID-19 pandemic) 2021 ERC guidelines the use of ACDs is considered if high-quality manual CPR is not practical or is dangerous for the provider[71].

CONCLUSION

The use of ACDs in 'hostile' environments, both in in- and out-of-hospital cases of cardiac arrest, seems to be beneficial both regarding compressions' quality and especially the rescuers' safety (Figure 1) So far, while experimental data is extensive, real-life studies examining their use in non-friendly situations are still limited. Since high-quality CPR remains the key to successful resuscitation, their use in such difficult and "hostile" situations should be seriously taken into consideration. Noteworthy, such use is indeed implied by guidelines.

FOOTNOTES

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ORIGINAL ARTICLE

Retrospective Cohort Study

Utility of short-term telemetry heart rhythm monitoring and CHA_2DS_2-VASc stratification in patients presenting with suspected cerebrovascular accident

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Abstract

BACKGROUND

Inpatient telemetry heart rhythm monitoring overuse has been linked to higher healthcare costs.

AIM

To evaluate if CHA_2DS_2-VASc score could be used to indicate if a patient admitted with possible cerebrovascular accident (CVA) or transient ischemic attack (TIA) requires inpatient telemetry monitoring.

METHODS

A total of 257 patients presenting with CVA or TIA and placed on telemetry monitoring were analyzed retrospectively. We investigated the utility of telemetry monitoring to diagnose atrial fibrillation/flutter and the CHA_2DS_2-VASc scoring tool to stratify the risk of having CVA/TIA in these patients.

RESULTS

In our study population, 63 (24.5%) of the patients with CVA/TIA and telemetry monitoring were determined to have no ischemic neurologic event. Of the 194 (75.5) patients that had a confirmed CVA/TIA, only 6 (2.3%) had an arrhythmia detected during their inpatient telemetry monitoring period. Individuals with a

confirmed CVA/TIA had a statistically significant higher CHA_2DS_2-VASc score compared to individuals without an ischemic event (3.59 *vs* 2.61, $P < 0.001$).

CONCLUSION

Given the low percentage of inpatient arrhythmias identified, further research should focus on discretionary use of inpatient telemetry on higher risk patients to diagnose the arrhythmias commonly leading to CVA/TIA. A prospective study assessing event rate of CVA/TIA in patients with higher CHA_2DS_2-VASc score should be performed to validate the CHA_2DS_2-VASc score as a possible risk stratifying tool for patients at risk for CVA/TIA.

Key Words: Telemetry monitoring; CHA_2DS_2-VASc score; Arrhythmia; Atrial fibrillation

Core Tip: Inpatient telemetry monitoring can be a costly resource in hospitals. Inappropriate use of this clinical tool only increases burgeoning healthcare costs both to the patient and the hospital. Atrial fibrillation is a risk factor for stroke which is why telemetry is indicated for 24-48 h after a cerebrovascular accident. However, telemetry for all patients for this short period of time can be non-diagnostic. Our study shows telemetry can be better utilized in patients with higher risk factors for atrial fibrillation as seen with higher CHA_2DS_2-VASc scores, and this stratification of telemetry monitoring may allow appropriate allocation and use for patients in whom benefit will be derived.

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INTRODUCTION

Non-intensive-care inpatient telemetry monitoring is a widely used observation tool in cardiovascular medicine. The use of non-intensive-care telemetry is widely utilized in the setting of suspected cerebrovascular accident (CVA) or transient ischemic attack (TIA)[1]. One of the most common causes of CVA/TIA is atrial fibrillation (AFib). The 2018 stroke guidelines states that cardiac monitoring is recommended for atrial fibrillation as part of in-hospital secondary prevention. Cardiac monitoring should be performed for at least the first 24 h[2]. Telemetry monitoring is utilized in these cases to assess whether undiagnosed atrial fibrillation was the cause of their ischemic event. Past studies have demonstrated that the use of telemetry inpatient post-stroke to assess for the presence of these arrhythmias may contribute to an increased healthcare cost burden[3,4].

The overutilization of telemetry monitoring has been a frequent discussion regarding our nation's ever-increasing healthcare costs. The American Board of Internal Medicine's 2013 Choosing Wisely campaign emphasized avoiding inappropriate continuous use of telemetry monitoring in an attempt to decrease the cost of care and number of false positive errors which could negatively impact patient care [5]. In 2004, the American Heart Association (AHA) first issued a statement on telemetry monitoring indications in intensive care settings[3]. Since then, updated recommendations in 2017 have been published by the AHA in order to address the overuse of arrhythmia monitoring as well as other issues. The AHA recommends monitoring arrhythmias for 24-48 h after a stroke[6]. Dhillon *et al*[7] formulated inclusion and exclusion guidelines for which patients should need telemetry monitoring outside of the intensive care unit in an effort to decrease costs from overuse. The efficacy of these guidelines was tested in a retrospective study of 562 patients and found that no patient that was not indicated for telemetry had a clinically significant arrhythmia. This suggests that it is possible to narrow the indications for which patients should be on telemetry monitoring.

As atrial fibrillation is a common etiology of CVA/TIA, CHA_2DS_2-VASc is a clinical scoring tool used to evaluate the one-year risk of having a thromboembolic event in a non-anticoagulated patient with nonvalvular atrial fibrillation[8,9]. This clinical scoring tool uses age, sex, congestive heart failure, hypertension, thromboembolism history, vascular disease, and diabetes as risk factors, and assigns points to each risk factor. If the total score is greater than or equal to 2 points, current literature states that an oral anticoagulation strategy should be employed to reduce the annual risk of stroke[10]. In our study, we sought to evaluate if CHA_2DS_2-VASc scoring could be used to risk stratify patients with a possible diagnosis of CVA or TIA into telemetry monitoring indicated *vs* nonindicated group.

MATERIALS AND METHODS

A retrospective cohort study was performed at a tertiary-care safety-net community hospital between January 2014 and December 2016 with a total of 257 consecutive patients admitted with suspected CVA or TIA. Criteria for patient inclusion in the study was an admission diagnosis of CVA or TIA, lack of pre-existing atrial fibrillation, and admission with telemetry monitoring employed. Telemetry monitoring was performed for at least 24 h, consistent with current standards of care. CVA or TIA was confirmed *via* current diagnostic guidelines (including patient evaluation by the neurology consulting service and/or non-invasive brain imaging studies). The CHA_2DS_2-VASc score was calculated for each patient. Independent variable *t*-tests were performed using SPSS Statistics, version 16.0, when comparing patients with and without a final diagnosis of CVA or TIA.

RESULTS

The demographics of our study population can be seen in Table 1 and includes age, ethnicity, sex, body mass index, smoking, and history of dyslipidemia. Of the 257 patients included in our study, 75.5% (n = 194) patients had a confirmed ischemic event (CVA or TIA). Of these patients, only 2.3% (n = 6) were found to have atrial fibrillation or atrial flutter during their inpatient telemetry monitoring.

The mean and median CHA_2DS_2-VASc scores were found to be significantly different between patients that did and did not have a confirmed CVA/TIA (Table 2). The mean CHA_2DS_2-VASc score was higher in the group with confirmed CVA/TIA than in the group without an ischemic event (3.59 *vs* 2.61, $P < 0.001$). The median score was also found to be higher, with median score of 4 in patients with CVA/TIA compared to median score of 2 in patients without an event ($P < 0.001$).

DISCUSSION

Atrial fibrillation affects over 5 million people in the United States and increases the risk of stroke by 5-fold compared to the rest of the population[10,11]. The initial presentation of atrial fibrillation can be asymptomatic or subclinical[12]. The economic burden of people with previously unknown and asymptotic atrial fibrillation is estimated to be over 3 billion dollars[13,14]. Of those with atrial fibrillation, female sex is an established risk factor for stroke, cognitive dysfunction, and dementia[15-17]. Patients diagnosed with atrial fibrillation with a concerning CHA_2DS_2-VASc score should be treated with anticoagulation therapy to avoid major adverse cardiac and cerebrovascular events (MACCE). The AFIRE trial showed a temporal association between major bleeding and MACCE events, demonstrating the importance of optimal antithrombotic therapy and managing bleeding risk in patients with atrial fibrillation and stable coronary artery disease[18]. Direct oral anticoagulants are shown to be at least as efficacious and safe as warfarin among patients with non-valvular atrial fibrillation[19]. DOACs are shown to have lower MACE rates *vs* warfarin[20].

The CHA_2DS_2-VASc scoring tool has been validated to estimate the patient's stroke risk with atrial fibrillation[21,22]. Limited research has been done to demonstrate its utility in predicting the risk of ischemic stroke in patients without atrial fibrillation. Our findings show that there is a statistically significant increase in the CHA_2DS_2-VASc score for patients with a confirmed ischemic event (3.59 *vs* 2.61, $P < 0.001$). Patients with ischemic events had their CHA_2DS_2-VASc score clustered on the higher end of the scores. Similarly, those patients without an ischemic event had their scores clustered towards the lower end of the score.

Of the 75.5% (n = 193) of patients that had a confirmed CVA/TIA, only 2.3% (n = 6) of these were found to have newly diagnosed atrial fibrillation. In a 2016 meta-analysis, Demeestere *et al*[23], detected atrial fibrillation in only 2.2% of patients with large-vessel CVA, and 2.4% of patients with small-vessel CVA. Moreover, a 2016 meta-analysis by Korompoki *et al*[24], found that atrial fibrillation was detected in 4% of patients post-TIA. These detection rates increased over time with an increased duration of monitoring. A meta-analysis of 32 studies showed the atrial fibrillation detection after CVA/TIA was better detected with more prolonged periods of monitoring compared to standard telemetry[25]. A study conducted by Simova *et al*[1] showed ECG telemonitoring after cryptogenic stroke or TIA only resulted in detection of AF in 10 of 36 patients (27%). The therapeutic implication of this finding suggests the benefit of routine prolonged ECG monitoring in this group as opposed to short-duration (24-48 h) inpatient telemetry.

The yield of telemetry use in this patient population is low, despite atrial fibrillation being a common cause of CVA/TIA. This presents a possible area in which we can safely reduce the amount of telemetry monitoring to only 24 h while inpatient or even possibly forgo monitoring completely in very low risk patients. Given the burden atrial fibrillation has on the general population, novel methods of screening are available and can be more cost effective[26]. Employment of wearable wireless continuous electrocardiographic (EKG) patches allows for one-to-two-week telemetry monitoring compared to the traditional 24–48-h Holter monitoring. This patient friendly approach can transmit telemetry recordings

Table 1 Demographics of the study population, *n* (%)

Variable	Confirmed CVA/TIA (*n* = 194)	Absent CVA/TIA (*n* = 63)
Mean age (yr)	67.54	58.54
Ethnicity		
White	105 (54.12)	32 (50.79)
Black	70 (36.08)	22 (34.92)
Other	19 (9.80)	9 (14.29)
Gender		
Men	93 (47.94)	24 (38.10)
Women	101 (52.06)	39 (61.90)
Mean BMI	27.36	29.10
Dyslipidemia	108 (55.70)	22 (34.90)
Smoking	54 (27.83)	14 (22.20)

CVA: Cerebrovascular accident; BMI: Body mass index; TIA: Transient ischemic attack.

Table 2 CHA_2DS_2-Vasc scores of patients with confirmed cerebrovascular accident /transient ischemic attack *vs* absent cerebrovascular accident /transient ischemic attack, *n* (%)

CHA_2DS_2-Vasc	Confirmed CVA/TIA (*n* = 194)	Absent CVA/TIA (*n* = 63)
0	11 (5.70)	4 (6.35)
1	26 (13.40)	19 (30.16)
2	24 (12.37)	10 (15.87)
3	29 (14.95)	15 (23.81)
4	42 (21.65)	4 (6.35)
5	26 (13.40)	4 (6.35)
6	20 (10.31)	4 (6.35)
7	11 (5.67)	3 (4.76)
8	5 (2.55)	0 (0.00)
Mean	3.59	2.61[a]
Median	4	2[a]

[a]*P* value < 0.001 on Mann-Whitney *U* Test. CVA: Cerebrovascular accident; TIA: Transient ischemic attack.

to health care providers for real time detection of cardiac events[27]. Studies have shown that the adhesive patch monitors detect more events than the conventional Holter monitor[28]. Recent developments have shown that wearables, such as smart watches, are an effective method of screening for atrial fibrillation in the general population. The Apple Heart Study used the Apple Watch in concurrent use with the current standard of diagnosing paroxysmal arrhythmias, the EKG patch, and showed that the positive predictive value of the tachograms was 0.71 (95%CI: 0.76-0.92)[29]. In addition to smart watches, portable single lead EKGs and phone applications can also be used to record palpitation events[26]. The Kardia Band designed by AliveCor mimics lead I and was designed to be used as an accessory for the Apple Watch. It was able to correctly detect atrial fibrillation with a sensitivity of 93% (95%CI: 86%-99%) and an 84% specificity (95%CI: 73%-95%)[30]. The Cardio Rhythm app for the iPhone uses the phone's camera to act as a light sensor in order to obtain heart rate measurements. The app is not used for continuous rhythm monitoring but can be used for sporadic heart rate checks or during symptoms of palpitations. It was able to detect atrial fibrillation with a sensitivity of 92.9% (95%CI: 77%-99%) and a specificity of 97.7% (95%CI: 97%-99%)[31]. Significant gaps of knowledge remain regarding the optimal length and yield of long-term inpatient monitoring beyond the recommended 24-h inpatient telemetry monitoring[32]. Future research should be done to evaluate

the percentage of detected atrial fibrillation in patients with confirmed ischemic events with outpatient cardiac rhythm monitoring of different lengths of time.

A total of 24.5% (n = 63) of patients in this study that were placed on telemetry monitoring for suspected CVA/TIA did not have a confirmed ischemic event per neurology evaluation. Given that the use of telemetry requires additional staff and hospital resources, increased cost burden, and is a limited resource in hospitals, efforts should be made to limit its use. Our findings suggest that the CHA_2DS_2-VASc score may be a valuable scoring tool to help risk stratify patients at risk for CVA/TIA and could thereby reduce the need of inpatient telemetry monitoring in patients suspected to have a CVA/TIA that have a low CHA_2DS_2-VASc score. Our study was limited by the small sample size of the study group. Additional studies with a larger sample size would allow for more statistical analysis of the utility of CHA_2DS_2-VASc in predicting CVA/TIA. Risk stratifications of patients can help reduce the use of unnecessary telemetry monitoring, especially in resource-limited hospitals.

CONCLUSION

Inpatient telemetry monitoring can be a costly resource in hospitals. Inappropriate use of this clinical tool only increases burgeoning healthcare costs both to the patient and the hospital. Atrial fibrillation is a risk factor for stroke which is why telemetry is indicated for 24-48 h after a CVA. However, telemetry for all patients for this short period of time can be superfluous and costly. Our study shows telemetry can be better utilized in patients with higher risk factors for atrial fibrillation as seen with higher CHA_2DS_2-VASc scores, and this stratification of use of telemetry monitoring will allow appropriate allocation and use for patients in whom benefit will be derived.

ARTICLE HIGHLIGHTS

Research background

Non-intensive-care inpatient telemetry monitoring is a widely used observation tool in cardiovascular medicine.

Research motivation

Inpatient telemetry heart rhythm monitoring overuse has been linked to higher healthcare costs.

Research objectives

Our study aimed to evaluate if CHA_2DS_2-VASc score could be used to indicate if a patient admitted with possible cerebrovascular accident (CVA) or transient ischemic attack (TIA) requires inpatient telemetry monitoring.

Research methods

A retrospective cohort study was performed at a tertiary-care safety-net community hospital between January 2014 and December 2016 with a total of 257 consecutive patients admitted with suspected CVA or TIA. Telemetry monitoring was performed for at least 24 h, consistent with current standards of care. CVA or TIA was confirmed *via* current diagnostic guidelines (including patient evaluation by the neurology consulting service and/or non-invasive brain imaging studies). The CHA_2DS_2-VASc score was calculated for each patient. Independent variable *t*-tests were performed using SPSS Statistics, version 16.0, when comparing patients with and without a final diagnosis of CVA or TIA.

Research results

Individuals with a confirmed CVA/TIA had a statistically significant higher CHA_2DS_2-VASc score compared to individuals without an ischemic event (3.59 *vs* 2.61, $P < 0.001$).

Research conclusions

Given the low percentage of inpatient arrhythmias identified, further research should focus on discretionary use of inpatient telemetry on higher risk patients to diagnose the arrhythmias commonly leading to CVA/TIA.

Research perspectives

A prospective study assessing event rate of CVA/TIA in patients with higher CHA_2DS_2-VASc score should be performed to validate the CHA_2DS_2-VASc score as a possible risk stratifying tool for patients at risk for CVA/TIA.

FOOTNOTES

Author contributions: Aydin T, Zeltser R, Makaryus AN performed the research; Bhuiya T and Zeltser R performed the statistical analyses in the paper; Zeltser R and Makaryus AN designed the research and contributed to the analysis; Bhuiya T, Roman S, Aydin T, Patel B, Makaryus AN, wrote the paper; Zeltser R, and Makaryus AN supervised the report.

Institutional review board statement: The study was reviewed and approved by our institutional review board (IRB) as an expedited study (IRB#16-093).

Informed consent statement: This research was a retrospective anonymized evaluation and informed consent was not required for IRB approval of this expedited study. The information was recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Our IRB approval document is provided separately.

Conflict-of-interest statement: Authors of no conflict of interest to disclose.

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SYSTEMATIC REVIEWS

Safety and efficacy of balloon angioplasty compared to stent-based-strategies with pulmonary vein stenosis: A systematic review and meta-analysis

Pradyumna Agasthi, Srilekha Sridhara, Pattara Rattanawong, Nithin Venepally, Chieh-Ju Chao, Hasan Ashraf, Sai Harika Pujari, Mohamed Allam, Diana Almader-Douglas, Yamini Alla, Amit Kumar, Farouk Mookadam, Douglas L Packer, David R Holmes Jr, Donald J Hagler, Floyd David Fortuin, Reza Arsanjani

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Abstract

BACKGROUND

Pulmonary vein stenosis (PVS) is an uncommon but known cause of morbidity and mortality in adults and children and can be managed with percutaneous re-vascularization strategies of pulmonary vein balloon angioplasty (PBA) or pulmonary vein stent implantation (PSI).

AIM

To study the safety and efficacy outcomes of PBA *vs* PSI in all patient categories with PVS.

METHODS

We performed a literature search of all studies comparing outcomes of patients evaluated by PBA *vs* PSI for PVS. We selected all published studies comparing PBA *vs* PSI for PVS with reported outcomes of restenosis and procedure-related

complications in all patient categories. In adults, PVS following atrial fibrillation ablation and in children PVS related to congenital etiology or post-procedural PVS following total or partial anomalous pulmonary venous return repair were included. The patient-centered outcomes were risk of restenosis requiring re-intervention and procedural-related complications. The meta-analysis was performed by computing odds ratios (ORs) using the random effects model based on underlying statistical heterogeneity.

RESULTS

Eight observational studies treating 768 severe PVS in 487 patients met our inclusion criteria. The age range of patients was 6 months to 70 years and 67% were males. The primary outcome of the re-stenosis requiring re-intervention occurred in 196 of 325 veins in the PBA group and 111 of 443 veins in the PSI group. Compared to PSI, PBA was associated with a significantly increased risk of re-stenosis (OR 2.91, 95%CI: 1.15-7.37, P = 0.025, I^2 = 79.2%). Secondary outcomes of the procedure-related complications occurred in 7 of 122 patients in the PBA group and 6 of 69 in the PSI group. There were no statistically significant differences in the safety outcomes between the two groups (OR: 0.94, 95%CI: 0.23-3.76, P = 0.929), I^2 = 0.0%).

CONCLUSION

Across all patient categories with PVS, PSI is associated with reduced risk of re-intervention and is as safe as PBA and should be considered first-line therapy for PVS.

Key Words: Pulmonary veins; Pulmonary vein stenosis; Constriction; Balloon angioplasty; Stents; Drug-eluting stents

Core Tip: 81.5% of patients with pulmonary vein stenosis undergoing a transcatheter intervention reported symptom of dyspnea. Pulmonary vein stent implantation (PSI) was superior to pulmonary vein balloon angioplasty (PBA) in preventing restenosis of the pulmonary vein. No difference in procedural related complications was noted between PSI and PBA. Differences in peri-procedural anticoagulation strategies between studies could have affected the outcome.

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INTRODUCTION

Catheter ablation for atrial fibrillation in adults involves the use of radiofrequency energy to electrically isolate the pulmonary vein[1]. As injured tissue heals scar tissue extends deeper into vein from the ostium leading to pulmonary vein stenosis (PVS). Cryoballoon ablation therapy for atrial fibrillation can have similar consequences[2]. With increased utilization of techniques aimed to reduce PVS such as antral isolation, 3-dimensional mapping and use of intra-cardiac ultrasound, the incidence of PVS has declined substantially from 20%-40% to 1%-1.5% currently[3]. In children, PVS can be primary (idiopathic) or secondary (post-surgical) following repair of total or partial anomalous pulmonary venous return[4], post pulmonary vein isolation and in Fibrosing Mediastinitis, where the patients develop severe pulmonary vein stenosis which is challenging to treat. Patients with severe PVS report symptoms of pleuritic chest pain, cough, hemoptysis and dyspnea on exertion. Untreated severe PVS can be progressive leading to irreversible lung parenchymal damage, pulmonary hypertension, heart failure and death[5].

Percutaneous intervention with balloon angioplasty (PBA) or pulmonary vein stent implantation (PSI) is the current treatment modality in adults. Re-stenosis risk after percutaneous interventions is higher in all patient categories and there is increasing adoption of stent-based strategies[6]. Available literature on this topic reports risk of restenosis with balloon angioplasty in the range of 44%-73%[6-8] and risk of re-stenosis of stent-based strategies over 16 years is 18%[8]. PVS confers poor prognosis in children and is conventionally treated with catheter intervention including PBA/PSI and/or surgery.

The former has been considered as a palliative approach. The mortality rate is as high as 47% at a median follow-up of 2 mo and re-intervention appeared to improve survival[5] and children with bare metal stents had better survival compared to drug-eluting stents (DES) and biliary atresia (BA)[9]. This may be dependent on the vessel size and on adjunctive therapy. The aim of this study is to perform a comprehensive analysis of safety and efficacy outcomes of percutaneous re-vascularization strategies of BA *vs* stent-based strategies for PVS in all patient categories.

MATERIALS AND METHODS

Protocol and registration

The protocol detailing the methods of the systematic review and meta-analysis was registered on the International Prospective Register of Systematic Reviews. The current meta-analysis was performed using the guidelines set by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[10]. Ethical review and approval were waived for this study, as our study is a meta-analysis and involves no interaction with human subjects and access to any subject identifiers.

Study identification and search strategy

We performed a comprehensive search for studies comparing PBA *vs* PSI in patient with PVSs using scientific databases (PubMed, EMBASE, Cochrane, Web of science, Scopus) from inception to December 2019. The search terms were pulmonary vein stenosis, balloon angioplasty, pulmonary balloon angioplasty, stents. The last search was run on December 31st, 2019. The authors (PA and SS) developed the search strategy along with a clinical information specialist (DA–D). The authors have read the PRISMA 2009 Checklist, and the manuscript was prepared and revised according to the PRISMA 2009 Checklist. Details of the search strategy are provided in the Supplementary Table 1-PRISMA checklist.

Study selection

Initial screening of the search results was performed by two reviewers (PA and SS). Title and abstract screening were first performed followed by comprehensive review of the entire manuscripts. When inconsistencies in screening were found and no consensus was reached a third reviewer (RA) casted the deciding vote.

Eligibility criteria

We selected all published studies comparing PBA *vs* PSI for PVS with reported outcomes of re-stenosis and procedure-related complications in all patient categories. In adults, PVS following atrial fibrillation ablation and in children PVS related to congenital etiology or post-procedural PVS following total or partial anomalous pulmonary venous return repair are included. All types of stents are included. No restrictions on study selection based on outcomes were used. Studies which assessed stent-based strategies without PBA group, abstracts which are published without full text publications and studies lacking endpoint measures were excluded.

Data extraction and quality assessment

For all the studies included, we extracted: (1) Study participants characteristics including age, gender, imaging modality after ablation, frequency of clinical symptoms related to PVS, study's inclusion criteria; (2) types of intervention- PBA *vs* PSI, stent size, post-intervention antiplatelet therapy and follow up imaging; and (3) outcome measures including re-stenosis requiring re-intervention and procedure-related complications. Cochrane Consumers and Communication Review Group's data extraction template was used to develop a standardized data extraction sheet for screening studies. The two authors independently collected the data and kappa values were used to report agreement measures. The primary outcome was re-stenosis requiring re-intervention and the secondary outcome was major complications related to procedures including death, major adverse cardiac and cerebrovascular events, major in-hospital complications requiring prolonged hospitalization or additional therapy (*i.e.* major bleeding or vascular complication, cardiac tamponade)

Quality assessment of studies, risk of bias

The study quality of included studies was assessed using the Newcastle-Ottawa Quality Assessment Scale for Cohort Studies as shown in Supplementary Table 2 (http://www.ohri.ca/programs/clinical_epidemiology/oxford.htm). Briefly, studies were quoted using prespecified items on patients' selection (representativeness and selection of patients, ascertainment of exposure, demonstration that outcome of interest was not present at the start of the study), comparability of cohorts based on the design or analysis, and assessment of outcomes (recording, adequacy of follow-up including length of follow up). Ratings for each item were added to provide a study quality score (maximal score, 9). Two independent reviewers (PA and SS) performed the Newcastle-Ottawa Scale grading. Discrepancies were resolved by consensus.

Method of analysis

The meta-analysis was performed by computing odds ratios (ORs) using the random effects model based on underlying statistical heterogeneity. A biomedical statistician performed the statistical review of the study. We calculated the OR and 95% confidence intervals (CIs) for each treatment effect for each study and pooled the point estimates of OR from each study using the generic inverse-variance method of Der Simonian and Laird[10,11]. Stata SE Statistical Software: Release 14.1, College Station, TX: StataCorp LP, StataCorp 2015. I^2 statistics were used to test statistical heterogeneity. The I^2 statistics describes the percentage of variation across studies that is because of heterogeneity rather than those expected by random chance [$I^2 = 100\% \times (Q\text{-}df)/Q$].

A CI for I^2 was constructed using either (1) noncentral chi-squared distribution method of Hedges and Piggott (2001) or (2) test-based method of Higgins and Thompson. The heterogeneity of effect size estimates across these studies was quantified using the I^2 statistic. The I^2 statistic ranges in value from 0 to 100% (I^2 < 25%, low heterogeneity; I^2 = 25%–50%, moderate heterogeneity; and I^2 > 50%, substantial heterogeneity)[12]. Publication bias was assessed using a funnel plot and Egger's regression test[13] (P < 0.05 was considered significant). A summary of evidence table was created to summarize the main results (patient-centered outcomes) using the GRADE Pro tool [Guideline Development Tool (Software), McMaster University, 2015 (developed by Evidence Prime, Inc)][14]. Sensitivity analysis was performed for primary analysis through an influence analysis by omitting one study at a time.

RESULTS

Study selection

A total of 856 Citations were identified using Pubmed, EMBASE, Scopus, Web of Science, and Cochrane databases. We excluded 415 studies based on the title and abstracts. After these exclusions and screening rest of the studies in detail we found eight studies that met the inclusion criteria mentioned above. The PRISMA diagram was created for the systematic review Figure 1. Kappa for agreement on full text, and abstract inclusion was 0.89 (95%CI: 0.86-0.94).

Study and patient characteristics

Table 1 and 2 summarizes the study characteristics. The trials that were included were published between 2003 and 2019. Studies were observational prospective and retrospective cohort studies and had a follow-up duration of 6 mo to 48 mo. A total of 487 patients were included in this meta-analysis. Study population included children and adults; the age range of patients was 6 mo to 70 years. 67% of the study population were males, 81.5% of the study population reported symptoms of dyspnea and 8.4% of patients were asymptomatic. 768 severe PVS lesions were included from all studies. Severe pulmonary vein was defined as > 70% luminal stenosis of the pulmonary vein based on computed tomography (CT) imaging. For adults with PVS, the time between atrial fibrillation ablation/pulmonary vein isolation to the development of clinical symptoms ranged from 1 mo to 18 mo. The imaging protocols used to diagnose PVS were contrast-enhanced spiral CT scans, magnetic resonance imaging, lung perfusion scans. PVS was confirmed by invasive angiography. Procedural aspects consisted of right heart hemodynamic monitoring, selective pulmonary angiography, and access of left atrium by transseptal puncture. Interventions performed were predilation, gradual balloon dilation, stenting in a stepwise manner or primary stenting. Pulmonary vein surgery was required in 5 children in reintervention group with pericardial well procedure[5] and hybrid stenting was performed after cardiac arrest in the operating room in some children with precluding anatomic factors, difficult vascular access, multiple closely spaced ostium[9]. Post-procedural antiplatelet and anticoagulant therapy was employed to ensure vessel patency. CT imaging and other imaging modalities were employed to follow up patients (Table 3).

Structure of the meta-analysis

The study compared PBA with PSI for patients with PVS. Bare metal stents, DES and hybrid stents placed surgically in children were included in this meta-analysis.

Patient-centered outcomes

Risk of re-stenosis requiring re-intervention: The data were available for all the 8 studies including 487 patients. 196 events occurred in 325 PBA interventions and 111 events occurred in 443 PSI interventions. Results show that PBA is associated with a significantly higher risk of re-stenosis compared to PSI (OR 2.91, 95%CI: 1.15-7.37, P = 0.025). A high degree of heterogeneity was noted (I^2 = 79.2%). Figure 2 shows the forest plots analysis for this outcome.

Risk of procedure-related complications: The data was available for 3 studies, 7 events occurred in 122 PBA interventions and 6 in 69 PSI interventions. Overall results show that there is no difference in procedure-related complications between PBA *vs* PSI for PVS (OR: 0.94, 95%CI: 0.23-3.76, P = 0.929),

Table 1 Main demographics of patients treated with either balloon angioplasty or stenting included in meta-analysis

Ref.	Patients (*n*)	Mean age (yr)	Males (%)	Frequency of clinical symptoms; Dyspnea (%)	Hemoptysis (%)	Asymptomatic (%)	Severe PVS treated (*n*)
Qureshi *et al* [19]	19	51 ± 13	NA	95	63	5	37
Prieto *et al*[7]	44	53 ± 11	70	88	23	7	68
Neumann *et al* [6]	12	58	70	77	8	17	15
Fender *et al* [20]	113	50	77	67	27	0	178
Cory *et al*[5]	30	Median age-6.4 m	50	NA	NA	NA	58
Schoene *et al* [15]	39	62.1 ± 9.0	60	79	26	NA	61
Kurita *et al*[9]	31	7 mo	65	NA	NA	NA	53
Suntharos *et al* [8]	199	55 ± 12	78	83	13	13	319

NA: Not available; PVS: Pulmonary vein stenosis.

without heterogeneity (I^2 = 0.0%). The forest plot analysis for this outcome is shown in Figure 3. In a study by Prieto *et al*[7], one patient in PBA group while undergoing pulmonary vein (PV) dilation developed an intimal flap needing stenting and had a transient ischemic event without permanent debility. Two patients in the stenting group developed tamponade requiring evacuation of pericardial space but there was no mortality. In a study by Neumann *et al*[6], there were 3 adverse events- one patient developed hemoptysis immediately after dilation of the left upper PV which stopped 10 min after protamine administration, one patient developed small dissection of the left upper PV during dilation before stenting distally with clinical hemoptysis which resolved by additional stenting of the vein distal to the original stenosis and allergic reaction to the contrast agent used was seen in one patient. In a study by Schoene *et al*[15], major events in PBA group were 2 wire-induced PV perforations with tamponade managed by pericardiocentesis and 2 balloon-induced PV ruptures with tamponade managed by urgent surgical repair in one and emergency stenting and pericardiocentesis in another. In the stent group, an acute stent thrombosis resulting in a stroke occurred which was complicated by intracerebral bleeding with thrombolytic therapy use but there was no mortality. Supplementary Tables provide further information regarding outcomes in the included studies (Supplementary Tables 3 and 4).

Sensitivity analysis: The funnel plot distribution of outcomes was derived from the standard error of the logarithm OR plotted against the OR of re-stenosis and procedure-related complications, respectively (Supplementary Figures 1 and 2). Influence analysis demonstrated that no single study significantly altered the summary ORs for the primary or secondary outcome, because the exclusion of each study did not alter the point estimate outside the 95%CI (Figure 4 and 5).

DISCUSSION

The analysis examines the safety and efficacy of intervention with PBA *vs* PSI in patients with PVS. The principal findings of our study include (1) Similar safety profile of PBA *vs* PSI in the management of PVS; and (2) A higher risk of re-stenosis with PBA in comparison to PSI in patients with PVS. The PSI demonstrated a lower risk of re-stenosis can be attributed to the use of stents in patients with higher risk and the use of devices not particularly designed for PVS intervention. A follow-up with cardiac imaging every 3-6 mo is usually done in patients with asymptomatic PVS with about 50%-70% stenosis, particularly with ipsilateral PVS, and revascularization is considered when the PVS progress to severe grade defined as luminal stenosis > 70% by CT imaging[16]. Intervention needs to be performed urgently in patients with concomitant ipsilateral PVS in order to prevent potential progressive vascular fibrosis, occlusion, atrophy, and congestion with consequent lung infarction[17].

In the advent of suboptimal results of angiography and the occurrence of complications post-dilation, an acute mechanical benefit is provided well by stents compared to PBA. In addition, it is suggested that there is a time-dependent reduction in patency of the vessel post-PBA, making stenting favored in terms of long-term advantages[18]. This can be ascribed to the pathophysiological mechanisms of the venous

Table 2 Clinical characteristics of patients treated with either balloon angioplasty or stenting included in meta-analysis

Ref.	Study type	Enrolment Period	Main inclusion criteria	Imaging after ablation	Mean time between PVI and clinical symptoms	Revascularization approach	Stent size	Acute angiographic success	Primary outcome at follow-up	Follow-up
Qureshi *et al*[19], 2003	*Observational retrospective study*	2000-2002	Severe PVS with clinical symptoms	CT-scans in symptomatic patients	4 mo	Stepwise	4-10 mm	NA	Freedom of reinter-vention	10 ± 9 mo
Prieto *et al* [7], 2008	*Observational retrospective study*	2000-2007	Severe PVS with clinical symptoms	CT-scans, lung perfusion scans in symptomatic patients	11.5 mo	Stepwise/primary stenting	8-10 mm	Residual stenosis ≤ 30%	Recurrence of symptoms requiring reintervention	25 ± 21 mo
Neumann *et al*[6], 2009	*Observational prospective study*	2003-2005	Severe PVS (> 70%) with clinical symptoms and/or significant perfusion defect	Surveillance imaging with MRI, lung perfusion scans, CT scans, TTE every 3 mo	NA	Stepwise (if rebound stenosis was observed after balloon dilatation)/primary stenting	8-12 mm	NA	Clinically symptomatic restenosis	48 mo
Fender *et al* [20], 2016	*Observational prospective study*	2000-2014	Severe PVS (> 75%) with clinical symptoms	Surveillance imaging with CT-scans at 3 mo + CT-scans and lung perfusion scans in symptomatic patients	4.0 ± 3.0 mo	Stepwise	6-10 mm + DES 4 mm	Residual stenosis < 20%	Clinically symptomatic restenosis	48 mo
Cory *et al* [5], 2017	*Observational retrospective study*	2005-2016	Catheter intervention for PVS for patients < 18 yr	NA	NA	Stepwise/primary stenting	Median-DES 4 mm, BMS 5 mm	NA	Mortality following transcatheter PV intervention	Median of 30.6 mo
Schoene *et al*[15], 2018	*Observational retrospective study*	2004-2017	Symptomatic PVS with > 70% in a single stenosis or > 60% in multiple ipsilateral stenosis	Initial screening process from 2004-2007- TEE 6-12 mo after PVI or when symptomatic, subsequent CT or MRI. Screening terminated in 2008, symptomatic patients underwent CT, MRI and/or PV angiography	10.2 ± 8.0 mo	Stepwise/primary stenting	Median stent- 7 mm × 20 mm, DES 5 mm	Residual stenosis < 10%-20%	Restenosis rate following transcatheter intervention	Median of 6 mo
Kurita *et al* [9], 2019	*Observational retrospective study*	2001-2017	PVS associated with total anomalous pulmonary venous connection and isolated congenital PVS	Combination of ultrasound, CT and angiography	Median 7 from birth	Stepwise/primary stenting-PCI/hybrid surgery	3-8 mm	NA	In-stent restenosis following stent placement using CT or angiography ≥ 50% higher stenosis of stent size	19 mo
Suntharos *et al*[8], 2019	*Observational retrospective study*	2000-2016	PVS after PVI undergoing PCI	CT-scan pulmonary vein protocol, quantitative lung perfusion scan	NA	Stepwise/primary stenting	3-16 mm	NA	Freedom of reinrevention	Median follow up-17 mo

CT: Computed tomography; DES: Drug-eluting stents; NA: Not available; PVI: Pulmonary vein isolation; PVS: Pulmonary vein stenosis; PV: Pulmonary vein; TEE: Transesophageal echocardiography; MRI: Magnetic resonance imaging; PCI: Percutaneous interventions.

system as well as the histological features. This ensues from post-thrombotic fibrosis inside and around the vein, with extravenous compressive bands and accompanying perivenous fibrosis leading to the obstructive processes in intima at ablation sites, which also involves the distal sites to PV ostia. Stenting

Table 3 Follow up characteristics after revascularization

Ref.	Antiplatelet therapy	Imaging modalities	Restenosis definition
Qureshi *et al* [19], 2003	NR	CT-scans every 3 mo	PV narrowing > 70% of the original PV lumina
Prieto *et al*[7], 2008	NR	CT-scans, lung perfusion scans at 3-12-24 mo	NR
Neumann *et al* [8], 2009	ASA+Clopidogrel+Coumadin for 3 mo	CT-scans, lung perfusion scans every 3 mo	PV narrowing > 70%of the original PV lumina before PVI
Fender *et al* [20], 2016	Coumadin+Clopidogrel	CT-scans, lung perfusion scans at 3-12-24 mo	PV narrowing > 75% in the previously treated PV
Cory *et al*[5], 2017	NA	Angiography	Vein loss defined as PV atresia or PVs of uncertain status in deceased patients
Schoene *et al* [15], 2018	ASA 4 weeks+Clopidogrel 6 mo+Coumadin or DOACs	CT-scans, MR imaging	PV narrowing > 70% in the previously treated PV
Kurita *et al*[9], 2019	ASA, Ticlopidin, Warfarin	CT or angiography	In stent restenosis: ≥ 50% luminal narrowing
Suntharos *et al* [8], 2019	Anticoagulation followed by low-dose aspirin	CT-scans, lung perfusion scans, angiography based on intervention-3 mo, 6 mo, 1yr	Severe restenosis/concern for progression to total occlusion

ASA: Acetyl salicylic acid; CT: Computed tomography; NA: Not available; NR: Not reported; PV: Pulmonary vein; PVI: Pulmonary vein isolation.

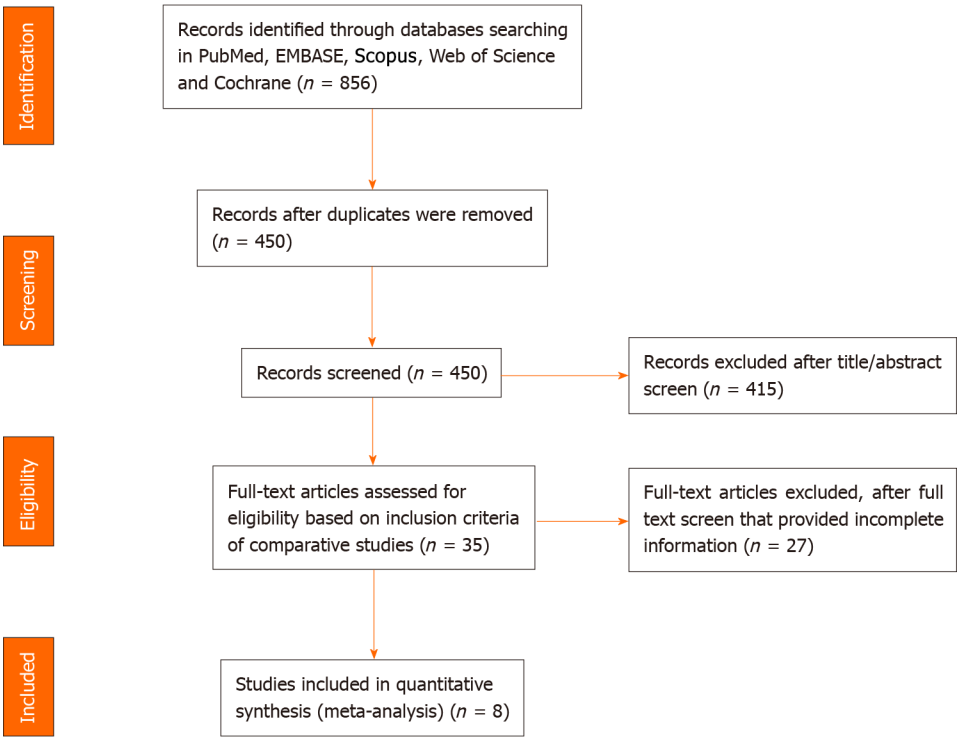

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Figure 1 PRISMA flow diagram for clinical study selection for meta-analysis.

may be able to provide an advantage against these pathophysiological mechanisms.

Studies show a high success rate and low re-stenosis rates of PSI compared to PBA, with longer freedom from re-stenosis[6]. Hence, stenting can be considered a first-line strategy. Studies have also consistently shown that large stent sizes, have excellent clinical outcomes and long-term patencies. Meta-analyses showed that long-term patency is better with large stent sizes of 9-10 mm[6,7]. The incidence of in-stent re-stenosis is shown to be less in large stents, as opposed to small stents[17,19,20]. Although stenting is widely used in the pulmonary vein, the operator needs to be careful due to the risk of protruding into the LA, jailing PV side branches, and crossing a low-flow distal side branch[18]. Other frequent complications, such as hemoptysis and self-limiting hemorrhages, have been found to be similar between the two groups. Revascularization is indicated in the advent of elevated PA pressure

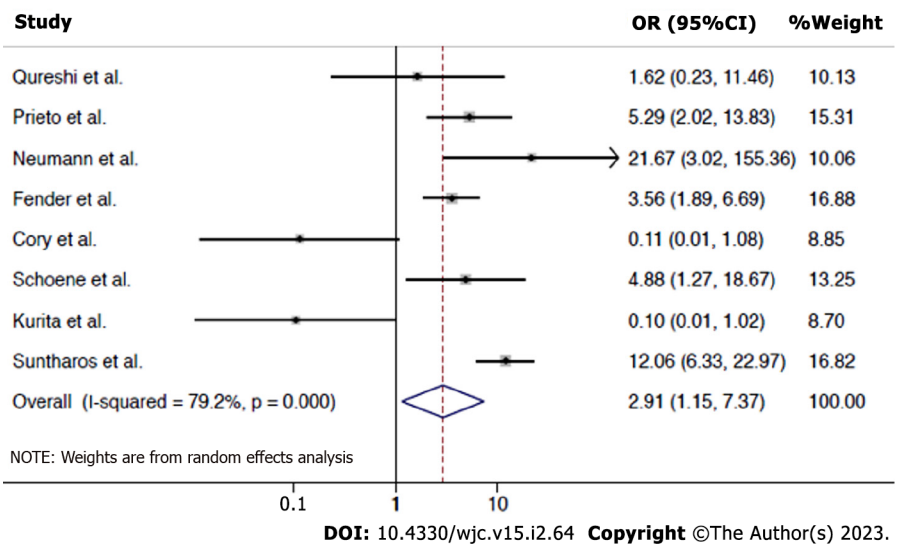

Figure 2 Forest plot for recurrent pulmonary vein stenosis in pulmonary vein balloon angioplasty group compared to pulmonary vein stent implantation group.

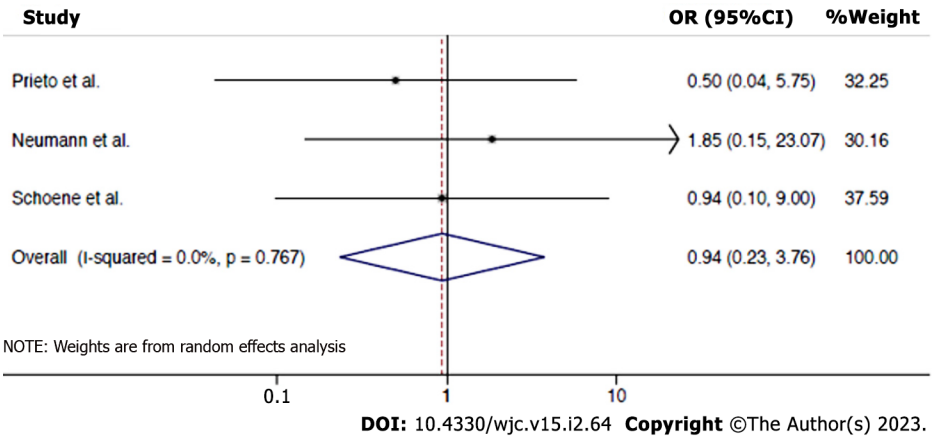

Figure 3 Forest plot for procedure related complications in pulmonary vein balloon angioplasty group versus pulmonary vein stent implantation group.

levels or the presence of typical symptoms. There is a chance of missing the diagnosis as the progression is unpredictable, and clinical symptoms may be atypical and can appear late. But early diagnosis and intervention are essential to prevent irreversible pulmonary damage.

Limitations of the study need to be acknowledged. The present study analyzes data comparing PBA and PSI from observational studies, but not randomized controlled trials. The analysis tends to be challenging to interpret when patients are treated with stenting after trial and failure of BA, as observed in some studies. In addition, procedural success and severe PVS definitions differ widely in studies, subsequently causing substantial heterogeneity. Also, the follow-up imaging techniques and protocols vary widely in the studies, which come into play when diagnosing post-procedural re-stenosis. Lastly, the antiplatelet/anticoagulation regimens post-procedure varies considerably in studies which might have possibly modified the treatment effect. The regimens were not consistently reported among different studies (Cory *et al*[5], Prieto *et al*[7], and Qureshi *et al*[19] didn't mention their regimens). The reported antiplatelet/anticoagulation regimens were also various, including 3 mo of dual-antiplatelet therapy[6], warfarin and aspirin/ticlopidine[9], and at least 6 mo of anticoagulation followed by long term aspirin[8]. Interestingly, the re-stenosis rates varied between the two studies included an anticoagulation agent (70% at 5 years, and 27% at 5 years), whereas the dual-antiplatelet regimen was associated with a 23% restenosis at about 4 years. This observation implies the post-procedural antiplatelet/anticoagulation regimens may have a minor role for restenosis.

Summary of evidence

The current analysis updates the summary of evidence by incorporating two recent observational

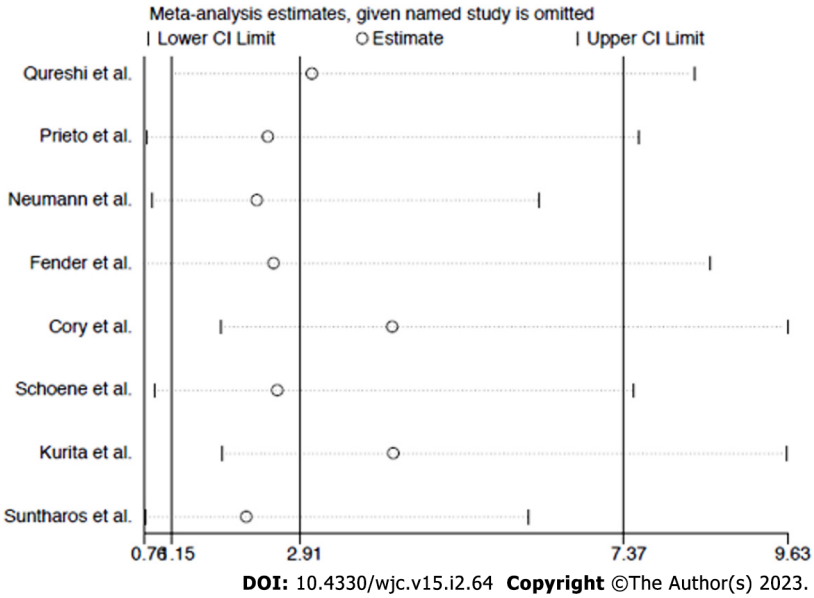

Figure 4 Sensitivity analysis for recurrent pulmonary vein stenosis.

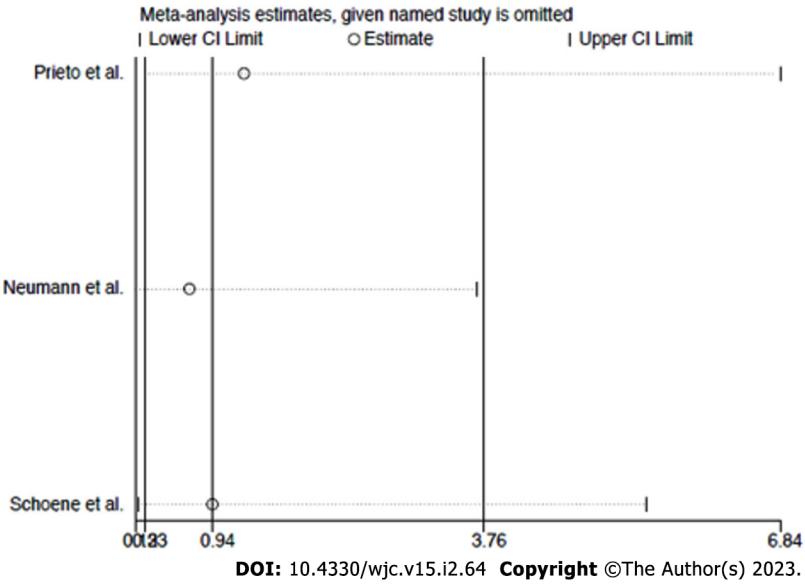

Figure 5 Sensitivity analysis for procedure related complications.

studies. Overall, we found sufficient evidence evaluating the comparative efficacy of pulmonary vein isolation (PVI) and PBA in treating patients with PVS. The outcomes with a moderate grade of certainty of evidence include pulmonary restenosis and procedure-related complications (Table 4).

CONCLUSION

Percutaneous re-vascularization with stents appears to be superior to PBA, in regard to re-stenosis and the need for re-intervention. Hence, stenting should be considered as the first line of choice over BA. A further follow-up to ascertain the real success of the intervention and the re-stenosis patterns is crucial.

Table 4 Summary of evidence

Outcomes	Anticipated absolute effects[a] (95%CI)		Relative effect (95%CI)	No. of participants (studies)	Certainty of the evidence (GRADE)[b]
	Risk with PSI	Risk with PBA			
Restenosis	251 per 1000	493 per 1000 (278 to 711)	OR 2.91 (1.15 to 7.37)	487 (8 observational studies)	⊕ ⊕ ⊕ ◯ MODERATE[c]
Procedure related complications	87 per 1000	82 per 1000 (21 to 264)	OR 0.94 (0.23 to 3.76)	191 (3 observational studies)	⊕ ⊕ ⊕ ◯ MODERATE[c]

[a]The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95%CI).

[b]GRADE Working Group grades of evidence: (1) High certainty: We are very confident that the true effect lies close to that of the estimate of the effect; (2) Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; (3) Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect; and (4) Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

[c]Rated down for imprecision as the 95% confidence interval overlaps with no effect and fails to exclude important benefit or important harm. PBA: Pulmonary vein balloon angioplasty; PSI: Pulmonary vein stent implantation.

ARTICLE HIGHLIGHTS

Research background

Pulmonary vein balloon angioplasty (PBA) and pulmonary vein stent implantation (PSI) are the two re-vascularization strategies used to manage pulmonary vein stenosis.

Research motivation

Both these strategies are widely used to treat pulmonary vein stenosis. Our study tends to explore outcomes and complications with each of these strategies

Research objectives

Our study tried to explore the safety and efficacy outcomes of two re-vascularization strategies Pulmonary vein balloon angioplasty *vs* pulmonary vein stent implantation in the management of pulmonary vein stenosis.

Research methods

The meta-analysis was performed by computing odds ratios using the random effects model based on underlying statistical heterogeneity.

Research results

The primary outcome of the re-stenosis requiring re-intervention occurred in 196 of 325 veins in the PBA group and 111 of 443 veins in the PSI group. Compared to PSI, PBA was associated with a significantly increased risk of restenosis (OR 2.91, 95%CI: 1.15-7.37, $P = 0.025$, $I^2 = 79.2\%$).

Research conclusions

Percutaneous re-vascularization with stents appears to be superior to PBA, in regard to re-stenosis and the need for re-intervention. Hence, stenting should be considered as the first line of choice over balloon angioplasty.

Research perspectives

A further follow-up to ascertain the real success of the intervention and the re-stenosis patterns is crucial.

FOOTNOTES

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