**Incidence and clinical course of limb dysfunction post cardiac catheterization: a systematic review.**

**Short running title:** Limb dysfunction after cardiac catheterization.

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**Abstract**

**Background**

We sought to systematically review the available literature on limb dysfunction after transradial or transfemoral cardiac catheterization.

**Methods & Results**

MEDLINE and EMBASE were searched for studies evaluating any transradial or transfemoral procedures and limb function outcomes. Data was extracted, results were narratively synthesized with similar treatment arms.

15 studies with 3616 participants were included in transradial access (TRA) group. 3 studies reported nerve damage with a combined incidence of 0.16%, 4 studies reported sensory loss, tingling and numbness with a pooled incidence of 1.61%. Pain after TRA was the most common form of limb dysfunction (7.77%) reported in 3 studies. The incidence of hand dysfunction defined as disability, grip strength change, power loss or neuropathy was low at 0.49%. Although RAO was not a primary end point for this review, it was observed in 3.57% of the participants in a total of 8 studies included.

 4 studies with 15,903,894 participants were included in the transfemoral access (TFA) group. Rate of peripheral neuropathy was observed at 0.004%, sensory neuropathy due to local groin injury and retroperitoneal haematomas was 0.04% and 0.17% respectively, whereas motor deficit due to femoral and obturator nerve damage was 0.13%.

**Conclusions**

Limb dysfunction post cardiac catheterization is rare, patients may have nonspecific sensory and motor complaints that resolve over a period of time.

**Key words:** Hand dysfunction, Leg dysfunction, distal extremity function, Cardiac catheterization.

**Introduction**

Trans-radial access (TRA) is now considered gold standard of care for percutaneous coronary intervention across many countries, with latest guidelines from European Society of Cardiology placing a class 1A level of evidence on use of TRA (1). TRA is associated with reductions in access site complications, major bleeding and mortality in high-risk patients compared to TFA(2-7). Whilst TRA is increasingly adopted as a first choice access site, limitations of the TRA approach include an increase in operator and patient radiation dose particularly in the early phase of training(8), a longer learning curve(9), challenges with small arterial loops in the forearm(10), radial artery spasm (RAS)(11) and radial artery occlusion (RAO)(12-14). Interest around the potential for upper limb dysfunction following TRA has come to fore in recent times particularly with increasing adoption of TRA(15-17). At a vascular level, neurovascular injuries such as intimal thickening, endothelial dysfunction and nerve damage following TRA may lead to complaints of upper limb dysfunction. One of the first studies led by Campeau et al(18) describing an early experience of TRA in 100 consecutive patients did not find any nerve damage associated with TRA at 3 months. In more contemporary practice, a prospective randomized study(15)of 338 participants reported that 10.5% developed extremity related complaints after transradial access.

In contrast, despite transfemoral access (TFA) being a widely used access site in many countries, there is limited data on lower extremity function following TFA. Access site related bleeding and vascular complications are known to occur and the incidence is much higher in TFA group compared to TRA both in randomized trials and observational studies(6, 19-23). However, the relationship between transfemoral access and lower limb dysfunction post cardiac cauterization is unclear. Finally, it is also important to note that the majority of studies reporting access site related limb dysfunction are limited to TRA and have not included any TFA patients to provide a comparison between the two access sites. In the current review, we systematically appraise the literature around incidence and long term clinical impact of upper and lower limb dysfunction post TRA and TFA respectively.

**Methods**

 We searched MEDLINE and EMBASE for TRA studies using the broad search terms: (radial, transradial, or radial artery) and (catheterization or catheterization or angiography or angiogram or angioplasty or percutaneous coronary intervention or PCI)) and (hand function or grip strength or disability or dysfunction or sensation or paresthesia or paralysis). TFA studies were searched for using the search terms: (femoral or transfemoral or femoral artery) and (catheterisation or catheterization or angiography or angiogram or angioplasty or percutaneous coronary intervention or PCI) and (leg or foot) and (function or strength or disability or dysfunction or paraesthesia or paralysis or sensation). The search results were reviewed by two independent judicators (MAU, CWW) for studies that met the inclusion criteria. The bibliographies of included studies and relevant reviewers were screened for additional studies.

 We included studies that evaluated any transradial procedure and evaluated hand function outcomes post transradial procedure and any transfemoral procedure and evaluated lower extremity function outcomes post transfemoral procedures. No control group was required so studies could be single arm. There were no restrictions based on sample size. There was no restriction on method of assessing hand function which included disability, nerve damage, motor or sensory loss. Where reported, we also collected data on vascular complications including vascular occlusions, pseudo aneurysm and hematoma formation. There was no restriction based on language of study.

 Data was extracted from each study into preformatted spreadsheets. The data were collected on the study design, year, country, number of participants with transradial and transfemoral procedures, age of participants, % of male participants, participant’s inclusion criteria, and measure of limb function and vascular complications, follow up and results for limb function and vascular complications. These results were narratively synthesized and trials with similar treatment arms were pooled using methods described previously(24). We conducted a pooled analysis of all studies that reported limb dysfunction post TRA or TFA cardiac catheterization. The number of patients with an event and the total patients were collected and the total percentages were determined. Where meta-analysis and pooled analysis was not possible descriptive synthesis was used to report study results.

**Results**

**Upper extremity dysfunction after transradial access**

A total of 15 studies reporting of hand dysfunction post TRA were included in the pooled analysis (Table 1). The process of study selection is shown in Figure 1. There were 12 cohort studies, 2 randomized control trials and 1 case-control study. There were 3616 participants in total with largest study of 1,283 and smallest study of 40 participants respectively. The mean age reported in 10 studies was 62.7 years and over two thirds of participants were male (78%). The results of the pooled analysis of hand function and vascular complications are presented in Table 2 and Table 3. These results are narratively described below.

***Nerve damage after transradial access***

A total of 3 studies reported a combined incidence of nerve damage post TRA at 0.16%(18, 25, 26) . The only observation of radial nerve damage was made by Zankl et al(25) in a study of 488 participants where only 1 patient (0.25%) experienced nerve damage post TRA. In contrast two other studies by Campeau18 and Benit et al(26) did not observe any nerve damage in their studies.

### ***Sensory loss, tingling and numbness after transradial access***

The pooled incidence of sensory loss, tingling and numbness was also low at 1.61% in 4 studies(27-30) . Tharmaratnam et al(27)in their retrospective case control questionnaire based study found the highest incidence of sensory abnormality in the form of pain and paresthesia in hand at 1.71% (22/1283) post TRA procedures.

***Pain after transradial access***

Pain was the most common complaint and reported at 7.77% in 3 studies(26, 27, 30). It was described as perioperative procedural pain. The largest study reporting pain post TRA procedure was conducted by Tharmaratnam et al(27)where pain was reported in 7.4% of participants.

***Hand function, disability, grip strength change, stiffness power loss and neuropathy after transradial access***

Hand function complications such as disability, grip strength, stiffness power loss and neuropathy were also low as the pooled rate was 0.49% across 6 studies(31-36). The largest study investigating hand function was conducted by Van Leeuwen (15) et al reporting an incidence of 9% and 11% for temporary (<30 days) and persistent (>30 days) upper limb complaints respectively. Same investigator in ACRA trial reported loss of hand function in approximately 4% of participants at 2 year follow up(36). However, majority of studies(31-35) evaluating hand function, disability, grip strength change, stiffness, power loss and hand complications, did not report any hand dysfunction at all.

***Vascular complications after transradial access***

Pooled incidence of vascular complications including bruising, hematoma, pseudo-aneurysm and dissection was reported at 2.42% among 9 studies(18, 25, 27-29, 31, 33, 35, 37). All these complications were based on clinical judgement and around perioperative time. For instance Lotan et al reported a 5% rate of vascular complications in the post-procedure assessment(29). Only 3 studies reported nearly 3% of access site related haematoma(27-29). None of the studies described clinically significant functional outcomes at follow up. Minor bruising related to access site was reported by Tharmaratnam et alin a cohort of 1,283 participants with an incidence of 2.3%(27).

***Radial artery occlusion after transradial access***

Overall incidence of RAO accounted for 3.57% of vascular complications across 8 studies(18, 25, 29, 31-33, 36, 37). Zankl et al.(25) noticed 10.4% of participants had RAO where spontaneous recanalization was observed in majority of participants at a 4 week follow up when the incidence of RAO was 4.3%. In contrast, only Wu et al.33 reported late RAO (14.7% of participants) at nearly 1 year follow up.

**Ascertainment of outcomes after transradial access**

In our pooled analysis of 15 TRA studies, we observed a significant heterogeneity in ascertainment of outcomes of hand dysfunction both in methodology and timing of ascertainment. For instance, the timing of measurement of outcomes and follow up varied between just after the procedure(35, 37) to 2 year(36). Similarly, studies employed various subjective questionnaires and test to measure different forms of hand dysfunction. Campeau(18) and Zankl(25) evaluated nerve damage at 1-3 months post procedure either by physical examination or telephonic questionnaire. Whereas, only Benit et al used electromyography (EMG) at 1 month follow up where no nerve damage was observed(26). The Majority of studies reported sensory loss by clinical examination based on patient symptoms. Only Van Leeuwen et al.(15, 30, 36) employed a well-recognized and widely accepted objective method in the form of Cold Intolerance Symptom Severity (CISS) questionnaire to assess the sensory component of hand function at 1 month, 1 and 2 year follow(15, 30, 36).

In addition, methods of measuring power strength ranged from Quick DASH questionnaire(15) to detailed measures of hand function by Wu et al(33), which included grip strength, palmar pinch, key pinch, tip pinch and endurance, and Wu reported no significant difference before and after transradial procedure. Finally, majority of studies used ultrasound(25, 29, 32, 33) to assess the incidence of radial artery occlusion post TRA.

**Limb dysfunction post transfemoral access**

In contrast to the 15 studies found in the TRA cohort, there were only 4(26, 30, 38, 39) studies that met the inclusion criteria for limb dysfunction post TFA with 15,903,894 participants. El-Ghanem et al queried NIS database to investigate incidence of femoral neuralgia (sensory and motor neuropathy of lower extremity) post TFA reporting only 597 events in a weighted sample of 15,894,201 participants (0.0004%)(39). In an another retrospective cohort study of 9,585 patients, only 20 patients developed femoral neuropathy(38). Assessment was based on clinical judgment and extensive review of patient's symptoms and disability following telephone interviews. There was an average delay of 37 hours from catheterization to recognition of symptoms. Almost 50% of patient complained of severe pain even before the onset of neuropathic symptoms. Motor neuropathy was observed in 13 out of 20 patients whereas, all the 20 patients reported sensory neuropathy. This translated into an overall rate of leg dysfunction of 0.21% in the study. (Table 4). Two distinctive patterns of sensory and motor complications were recognizable from the studies included in the TFA group as outlined below.

***Neuropathy due to retroperitoneal Haematoma***

Large retroperitoneal hematomas were the most common cause of sensory neuropathy across 1 study, due to involvement of femoral nerve and lateral femoral cutaneous branches and were observed in 0.17% of participants (16/9,585) ([38](#_ENREF_38)). Motor deficits of the femoral (weakness of quadriceps and psoas muscles) and obturator nerve (inability to adduct the thigh) was observed in 0.13% of participants (13/9,585). Only 1 patient in this group required surgical intervention pertaining to expanding retroperitoneal haematoma. As a result of this, 6 patients reported severe initial deficit (2 were unable to walk and 4 required assistance in form of walker, crutches and leg brace). The size of the retroperitoneal haematoma did not correlate with the severity of sensory or motor deficit(38).

***Neuropathy due to groin haematoma and false femoral aneurysm***

 Localized access site complications such as groin haematoma and femoral false aneurysm resulted in sensory neuropathy in 0.04% (4/9,585) of the patients due to involvement of the medial and intermediate cutaneous branches of the femoral nerve(38). Two patients were found to have aneurysms on clinical examination and confirmed with ultrasonography. The remaining 2 had groin haematoma out of which one required surgical drainage.

**Ascertainment of outcomes after transfemoral access**

We observed that the length of follow up ranged from 1 month(30) to 26 ± 17 months(38) across 4 studies. In first group, partial resolution of sensory neuropathy was observed at the time of discharge. 50% of patients had complete resolution of symptoms by the end of 2 months. On the other hand 5 patients had persistent sensory neuropathy at 41 month follow up. Motor symptoms resolved in all patients except one who occasionally required a stick to walk because of quadriceps weakness. All of the patients in second group had complete resolution of symptoms immediately after repair of false aneurysm and 5 months after drainage of groin haematoma. In one of the recent studies from contemporary practice, Van Leeuwen et al.(30) reported a higher incidence of lower extremity related symptom in their TFA cohort at 17.3% immediately post procedure which decreased to 11.5% at 1 month follow up respectively.

**Discussion**

In this systematic review, we narratively describe the incidence of limb dysfunction after TRA and TFA cardiac catheterization. We found that the incidence of limb dysfunction following TRA or TFA is very low at 0.26% and 0.21% respectively. We observed significant heterogeneity amongst the studies with regards to definition, method and timing of assessment of limb dysfunction. The most striking finding is that despite being the oldest and widely practiced access site for cardiac catheterization, limb dysfunction is rarely evaluated or reported after TFA. Finally, our study supports the fact that most operators whether radial or femoral very rarely refer patients for specialist input or for further rehabilitation as majority of the symptoms resolve without any significant long-term disability.

The exact mechanism of limb dysfunction (motor or sensory) following TRA or TFA cardiac catheterization is unclear though there are many possible explanations. Firstly, flexor carpi radialis, flexor pollices longus tendons and median nerve lie next to radial artery at the wrist from lateral to medial respectively and femoral nerve just lateral to femoral artery. These structures can be directly damaged during cannulation of the radial or femoral arteries. Direct injury and hematoma lead to oedema (inflammatory reaction) with secondary compression of underlying structures (e.g. carpel tunnel syndrome, compartment syndrome) leading to motor and sensory deficit. Additionally, extrinsic pressure to achieve haemostasis may lead to transient or permanent ischemia of the main nerves or branches resulting in motor or sensory deficit(18, 25-27, 29, 30, 32, 38). Haematoma formation(16) is a common manifestation of access site related bleeding, more frequently encountered in patients undergoing TFA cardiac catheterisation procedures. Large, rapidly expanding haematomas can also cause intrinsic compression of associated neurological structures resulting in neurological damage. Though this mechanism of neurological damage is not well reported in these studies, there are isolated case reports of such occurrences (40,41,42). Another mechanism for development of limb dysfunction is from direct ischaemic injury. For instance, radial artery occlusion is a recognized complication from transradial access(14, 15, 30) that can lead to transient or permanent mild ischemia of hand. Such ischemic insults following RAO may contribute to hand dysfunction. Interestingly in a recent study by Zwaan and colleagues, a higher incidence of RAO (9.8%) was observed in patients experiencing hand dysfunction compared to those with normal hand function (0% RAO)(43) . While in most patients there is collateral blood flow from the ulnar artery and palmar arches, the authors postulated that RAO may still lead to reduction in blood supply to hand muscles and ischaemia. In contrast, Van Leeuwen’s(36) ACRA trial reported no loss of hand function related to incompleteness of the palmar arches. In the RADAR study Valgimigli et al(31) employed a more objective method of detecting hand ischemia by measuring lactate in patients undergoing TRA with normal, intermediate and abnormal Allen’s test. Lactate did not differ among the 3 study groups after the procedure and more importantly there were no differences in handgrip strength test results and discomfort ratings across the three groups. It is important to note that anatomical variations may also play an important role in neurovascular injuries. For instance, radial artery anomalies such as high-bifurcating radial origins, full radial loops and extreme radial tortuosity(10) are well known to increase the risk of procedural failure via TRA. Increased instrumentation and catheter exchanges can also cause vascular damage both at the endothelial and vascular level. Furthermore, once trauma has occurred to the vasculature and nerves, its impact may depend on how early it is identified and managed. For example, a small hematoma may not be recognized until it has caused significant swelling and possible extension proximally or distally.

Our analysis demonstrates that pain and neurological symptoms were the most common form of limb dysfunction reported. The pooled incidence of pain post TRA and TFA was 6.67% and 0.21% respectively. Although, patients frequently reported pain following the procedure, the majority of these settled over time without any significant residual symptoms(38). Neurological symptoms can be more worrying as they can impair day to day function of the individual. In one of the landmark studies evaluating limb function post TRA or TFA, van Leeuwen and colleagues(30) reported that nearly 20% of the patients developed subjective neurological complications in the form of numbness, tingling, stiffness, and less power post TRA. Reassuringly the majority of these symptoms resolved at 30 days follow up. More recently, the investigators published the results of the same study(15) at one year follow up, illustrating although limb related complaints were reported equally in both TRA and TFA access groups, they diminished significantly over time without any clinical sequelae. The transient nature of these complications is important as resolution of symptoms raises doubt around the long term clinical relevance in clinical practice which supports the theory of temporary inflammatory reaction due to local injury leading to sensory and motor deficit.

There is currently no consensus regarding the definition for limb dysfunction post TRA or TFA cardiac catheterization and no agreement on the optimal method of assessing limb function. Studies to date have employed a whole spectrum of tests such as Visual Analogue Scale (VSA: a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured for example pain), Boston Carpel Tunnel Questionnaire (BCTQ: a measure of symptom severity and functional status), Disabilities of Arm, Shoulder and Hand (QuickDASH: a measure of physical function, symptoms, and its consequences on daily life) and Cold Intolerance Symptom Severity (CISS: a measure of intolerance to cold) questionnaire. It is important to note that these tests have been mainly developed and validated in non-cardiac intervention settings. In the evaluation of limb dysfunction, it is important to consider procedural and patient characteristics such as how challenging or traumatic the puncture was, size of sheath, number of catheters used, and presence of spasm or underlying peripheral vascular disease (PVD), diabetes and pharmacological agents used during the procedure. Post procedural factors like the method of achieving haemostasis, compression and any immediate complications may also play an important role. Whilst studies have been undertaken to systematically study hand dysfunction post TRA, there have been no studies that focus on lower limb dysfunction following TFA to date despite the femoral artery being used for cardiac catheterization for over 50 years. With the growth of larger bore femoral access for structural heart interventions that are becoming increasingly common practice, future work should focus on leg / foot dysfunction particularly in these clinical situations.

Our study is the first to compare and systematically present the incidence of limb dysfunction post TRA or TFA. We found that majority of the literature around limb dysfunction has been published in patients undergoing TRA and only 2 studies have assessed limb dysfunction post TFA. While we were able to provide a comprehensive summary of the current literature. Our review has few limitations. The evidence is poor and not of sufficient quality to perform meta-analysis. We also identified significant heterogeneity in the study designs and methodology such as the various ways of assessing limb function. However, our findings show that there are limited data on location, severity, causality, treatment and long term outcome of limb dysfunction after cardiac catheterization.

**Conclusion**

In conclusion limb dysfunction post TRA and TFA cardiac catheterization is a rare entity. There is a lot of variability in methodology and reporting of studies investigating limb dysfunction post TRA and TFA. Participants may have nonspecific sensory and motor complaints that resolve over a period of time. More robust and pragmatic approach is required in future studies to measure the clinical relevance of such complications.

**Discourse**

None relevant to this study.

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