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A pilot study of forearm microvascular impairment and pain while using a telephone.

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Abstract

Objective: To determine if using a telephone can induce forearm pain and ischemia.

Design: Prospective case-control trial.

Setting: Vascular laboratory in the university hospital in Angers between September 2018 and March 2019.

Participants: Fifteen apparently healthy subjects (controls) and 32 patients with suspected thoracic outlet syndrome (TOS) of vascular or non-vascular origin.

Intervention: Hand-holding a cellular phone to answer a call from investigators.

Main outcome measures: Presence of forearm fatigue or pain (primary outcome), ability to hold the phone with each hand for 1 minute (secondary outcome 1) and decrease in forearm transcutaneous oxygen pressure DROP index indicating forearm ischemia (secondary outcome 2). A DROP < -15 mmHg defined ischemia.

Results: Answering a phone call resulted in 25(78%) patients with forearm fatigue or pain and in 18 (56%) cases in the inability to hold the phone for 1 minute, on one or both arms in patients with suspected TOS, but never occurred in healthy volunteers ($P < 0.05$ and $p < 0.001$). The presence of ischemia was observed in one or both arms in 10 (31%) patients with proved TOS and was always associated to phone-induced pain. Three (20%) of the controls had phone-induced ischemia. All had asymptomatic TOS and remained asymptomatic during the phone test ($p=0.42$ from suspected-TOS patients).

Conclusion: The phone conversation resulted in pain in many patients with suspected TOS. Transcutaneous oximetry can document the underlying ischemia. Forearm phone-call-induced pain may be indicative of TOS provided that no earplug or headset is used.

Trial registration [ClinicalTrials.gov NCT03355274](https://clinicaltrials.gov/ct2/show/study/NCT03355274)

Keywords: Peripheral artery disease; Telephone, Provocative maneuvers; Ischemia.

Abbreviations:

DASH: Disability of the Arm and SHoulder

DROP: decrease from rest of oxygen pressure

DROPm : Minimal value of the DROP throughout a test

EAST: Elevated Arm Stress- Test

TcpO₂: transcutaneous oxygen pressure

TOS: thoracic outlet syndrome

Introduction

A spectacular change of the tools used by humans from prehistoric flints to cell phones has occurred through the ages. Similar to technological evolution, human shoulder anatomy has changed from our simian ancestors reducing the sub-clavicle space and leading to potential positional compression of the neurovascular axes [1]. In most cases this transient positional compression remains apparently asymptomatic, [2; 3] but acute complications may occur such as venous thrombosis or arterial emboli [4-10]. In some patients, repeated compression can result in debilitating symptoms referred to as “thoracic outlet syndrome” (TOS)[11]. These symptoms can severely impair quality of life either in professional activities or usual daily life [12-17]. There are billions of cell phone calls per day worldwide. The use of the telephone is one of the most commonly done actions in people’s daily routines. Many studies have focused on possible health consequences of chronic and prolonged use of cell phones on health [18; 19]. Amazingly, no study was performed to date to confirm whether the use of cell phones could be associated to forearm pain, specifically in patients with suspected TOS.

Further, most TOSs are considered of neural origin, but dynamic investigations during postural maneuvers are generally performed to detect vascular (arterial and/or venous) compression. We recently reported that transcutaneous oximetry was accurate to document ischemia during the Elevated Arm Stress Test (EAST) maneuver, also referred to as the Roos test [20], hypothesized that using a phone to answer a call could be responsible for forearm pain in adults, specifically when suspected of TOS. We also aimed to document the eventual presence of ischemia with transcutaneous oxygen pressure (T_{cp}O₂) measurements during the call.

Methods

Study protocol

Between September 2018 and February 2019, healthy, young individuals and patients referred to our laboratory for suspected TOS were screened for inclusion. We enrolled adult individuals willing to participate in the trial according to inclusion and exclusion criteria listed in table 1. The patients were fully informed about the study and its procedures. This research and all its procedures were performed in compliance with the principles outlined in the Declaration of Helsinki. The study was promoted by the University Hospital in Angers, approved by our institutional Ethics Committee, and was registered in Clinicaltrials.gov under Ref: NCT03355274.

Study population

At the time of study inclusion, we recorded subject demographics and conditions including: age, sex, presence of one or more cardiovascular risk factors (hypertension, diabetes mellitus, dyslipidemia, active smoking), history of chest or shoulder surgery, and any ongoing treatments. We also measured weight, height, systolic and diastolic blood pressures. Results from routine vascular laboratory ultrasound investigations performed prior to inclusion were encoded as confirming the “presence” or “absence” of arterial compression on each side, according to the patient’s medical record and were kept unknown to the investigators performing the fake call. Ultrasound investigations standard procedure includes an EAST maneuver and Adson’s tests as a

minimum, but these are not included in the study that focused only on the medical report for these investigations.

Interventions

We used a 3-probe TCM400 device (Radiometer, Copenhagen, DK) to measure transcutaneous oxygen pressure. Probes were fixed through a double sided adhesive ring to isolate from air on both the forearm and at the sub-clavicular level as previously reported [20]. After positioning the probes, a minimum of 20 minutes was required to reach TcpO₂ stable value due to local heating (44.5°C). Tcpo₂ values were recorded in real time on a 1Hz basis on a home-made program [21; 22] [20; 22; 23]. The program automatically converted to decrease from rest of oxygen pressure (DROP) index (the subtraction of chest changes from arm changes on each side). By design, DROP is equal to zero at baseline, and in case of ischemia is a negative value. It is expressed as a millimeter of mercury [20; 22; 23]. We evaluated positional clinical response to the EAST maneuver and then to using a cell phone on the right and then the left hand consecutively. The investigator repeatedly asked to report any symptoms (pain, fatigue, numbness, or tingling) experienced during the fake call on each arm. The subject was free to change hand if necessary due to symptoms and asked to do so in the absence of symptoms after a period of at least 1 minute. Forearm oximetry with a chest reference probe was used to search for ischemia during the call as a result of eventual arterial occlusion.

Outcomes and number of subjects calculation

The primary outcome was the presence of forearm pain or discomfort during the call on each arm. The secondary outcomes were the ability to hold the phone for one minute and the presence of forearm ischemia (arbitrarily defined as a minimal DROP index (DROP_m) below minus 15 mmHg) [20; 22]. We estimated that only half of the patients referred for suspicion of TOS would have clinical and ultrasound investigations confirming the presence of TOS and then aimed to recruit at least two times more TOS suspected patients than control subjects. We arbitrarily estimated for our primary outcome measure that one third of TOS suspected patients would have telephone induced symptoms while no patients of the control group would experience similar discomfort. With a ratio of the number of TOS to the number of controls of 2, the inclusion of a minimum of 9 control patients and 18 TOS patients was sufficient to reach a 5% alpha error and 1-beta error of 80%. [24]

Statistical analysis

Kolmogorov-Smirnov tests were used to test the distribution of variables and results are presented as mean +/- standard deviation for parametric, or median [25^o; 75^o centiles] for non-parametric continuous variables, and as number of cases (percentages) for categorical variables. In the between-group analysis, two-tailed Fisher exact tests were used for proportions, and unpaired t-test or Mann-Whitney for numerical values according to distribution. Then we calculated the diagnostic performance (sensitivity, specificity, positive predictive value, negative predictive value, and accuracy) in predicting the presence of TOS during vascular ultrasound investigations, based on the ability to hold the phone for a minimum of one minute. The last correlation of the minimal DROP value observed during the phone call and during the EAST maneuvers was estimated by Spearman's correlation coefficient. All tests were performed with

SPSS 15.0 for Windows (SPSS Inc.; LEAD tech Inc. 2006). For all tests, a two tailed $p < .05$ was used to define statistical significance.

Results

Study population

A total of 15 healthy individuals and 33 patients referred for the investigations of suspected TOS were deemed eligible for inclusion. One TOS patient was excluded because the phone test could not be performed due to time constraints. Although we recruited young and middle age subjects in both groups, baseline characteristics of enrolled participants differed between TOS patients and control individuals for age, weight and the prevalence of active smokers, as shown in table 2. No difference in the prevalence of ongoing treatments was found between TOS patients and controls, while 17 (53%) TOS patients and three (20%) control subjects had one or more cardiovascular risk factors ($p=0.056$ between the two groups).

In TOS suspected patients, 9 had unilateral and 15 had bilateral positive results on their routine ultrasound investigation report. Of the control subjects, 2 people were diagnosed with asymptomatic bilateral arterial impingement and one person with unilateral right arterial compression during the EAST manoeuvres.

Outcomes

Typical examples of TcPO₂ recordings are presented in Figure 1. During the EAST maneuver, DROPm was -22 [-49; -12] mmHg and was -10 [-20; -6] mmHg in the 64 arms of TOS-suspected patients and in the 30 arms of control subjects respectively ($p < 0.001$). During the phone test, DROPm was -7 [-11; -3] mmHg and was -6 [-10; -5] mmHg in the 64 arms of TOS-suspected patients and in the 30 arms of control subjects respectively ($p=0.726$).

As shown in figure 2, a significant correlation was found between the results of the minimal DROP observed during the EAST maneuver and on the same arm during the phone test. It should be noted that although the correlation was significant, the phone test reproduced, at best, the same level of ischemia as the EAST maneuver but in most cases resulted in less severe ischemia.

Table 3 reports the results for the primary outcome in TOS-suspected patients. As shown, 20 of the 32 patients with suspected TOS had pain during the phone test on one or both sides, five of the patients with negative routine investigations (non-arterial TOS or no TOS) had unilateral pain, three patients had no pain and negative routine investigations, and four patients had no pain despite the presence of abnormal ultrasound investigations. Note that no patient from the control group had pain during the phone test despite the presence of TOS in 3 of them during their routine investigations.

As a secondary outcome, 18 of the 32 (56%) TOS suspected patients were unable to hold the phone for one minute with one ($n=11$) or both ($n=7$) hands while all controls could do it. In the whole studied population, the inability to hold a phone for one minute showed 53.8% sensitivity,

81.0% specificity, 77.8% positive predictive value, 58.6% negative predictive value and 66.0% accuracy in predicting the presence of TOS during vascular ultrasound investigations.

As another secondary outcome, the inability to complete a one minute call with a single hand was associated to a significant decrease in DROP index in six cases only. A significant ischemia was observed but did not result in the inability to hold the phone for one minute in six hands of six different TOS suspected patients (with confirmed arterial compression during vascular ultrasound investigations in all cases) and in four hands of three control subjects (with three vascular ultrasound investigations indicative of arterial compression).

Discussion

This is the first prospective case control study evaluating the pain induced by answering a phone call in patients with suspected TOS. Our finding suggests that beyond the widely studied effect of chronic and prolonged use of cell phones on health [18; 19], pain while using a cell phone could be indicative of the presence of positional-induced arterial compression.

Many questionnaires have been proposed to standardize the report of forearm or shoulder disability by history. The most widely used questionnaires in TOS are the original or shortened versions of the “Disability of the Arm and SHoulder” (DASH) questionnaire [15; 25]. DASH includes symptoms observed while playing golf or tennis, hammering, washing floors or carrying a briefcase. While most of these activities are unlikely to be done by patients on a daily basis, telephone use is not suggested among proposed routine activities. To the best of our knowledge, the sole questionnaire including an item related to the use of a cell phone is the Cervical Brachial Symptom Questionnaire, but it is scarcely used in TOS [15; 26].

Beyond symptoms by history, a specific interest in the present study was the observation of forearm pain not only by history but also during a laboratory-based phone-test. Another original observation is the presence of ischemia in some of the patients reporting forearm pain during the phone call [20]. Clearly, not all suspect patients were positive for TOS during arterial ultrasound investigations and in patients with TOS, neural compression (or venous occlusion) shall not result in forearm ischemia. This is a possible explanation of TOS-suspected patients reporting symptoms without underlying ischemia on TcpO₂. Interestingly and inversely, three healthy individuals showed forearm ischemia but remained asymptomatic. The observation of asymptomatic ischemia in these three healthy individuals (at least by initial history) is consistent with the well-known prevalence of apparently asymptomatic TOS in the general population [27]. It is noteworthy that one of these three subjects called us two days after the study to report that “on second thought” she never used her phone without an earplug, and was unable to hold the overhead bar in the tram for more than a few tens of seconds. Another notable point is that the severity of ischemia as assessed by DROP calculation was generally lower during the phone test than during the EAST maneuver. We believe that this is due to the lower angle produced during the phone call than during the EAST maneuver.

Study limitations

The study has several limitations. First, we did not record the commercial brand name of the cell phone used and cannot exclude that our findings can depend on the phone weight. Second, no

rating of pain intensity was done. Some patients reported forearm discomfort or fatigue rather than pain, but these symptoms were intense enough to force them to change the hand used to hold the phone. Third, we studied an adult population, and cannot extend our results to children. This is unfortunate because in young people (10–24 years) the average number of calls per week is high (approximately 30/week) and the average time spent per week, making or receiving calls exceeds one hour [28]. Fourth, we did not focus on gender specific differences while these can influence the use of telephones [29]. Fifth, Tcpo2 is a time-consuming technique. Although it was of interest in this study for research purposes, it is unlikely to become a routine technique. Last, we cannot evaluate a duration that can be performed in asymptomatic users and thus face a barrier on the duration that can be sustained for the call in the asymptomatic group. Phone call duration is generally estimated to be approximately 2 minutes in the general young population [28].

Implications of this study

Using a cell phone seems to induce forearm pain in TOS-suspected patients, forcing the patients to regularly change the hand used to hold the telephone. This was never reported in previous studies focusing on subjective symptoms observed in cell phone users [30; 31]. Based on the present pilot study suggesting a prevalence of 60% painful phone tests in TOS-suspected patients, a prospective study should be done to confirm this proportion. Such a study would require the inclusion of more than 250 patients to reach a 5% margin of error and 90% confidence level. Another prospective study should be done to evaluate whether searching for forearm phone-induced pain by history could be useful in the clinical evaluation of patients suspected of TOS. On this perspective approach, it is likely that the specificity of phone-induced pain will be low for TOS (with five of the eight patients with negative ultrasound results showing phone induced unilateral or bilateral pain) and that many other forearm diseases are potentially resulting in such a discomfort. It should also be noted that when questioning the patient on arm symptoms during phone calls, the physician must have confirmation that the patients do not use headsets or amplifier earplugs to prevent the occurrence of symptoms. Thankfully, hands free calls are estimated to represent only 19% of all phone calls [28]. Few technical possibilities exist to replace Tcpo2. Various apps on cell phones allow for the measurement of temperature [32], pulse [33-35], and color of the skin [35]. Cell phones combining color, temperature and plethysmography analysis with automatic detection of the phone position could be able to automatically determine the presence of TOS induced ischemia during phone use and facilitate to identify the presence or absence of ischemia while using the telephone [36].

Footnotes

- Contributors: PA conceived the study. PA, PR, JH and SH shared the role for experiments. JP referred most patients and completed most medical files. PA and SH wrote the draft that was critically reviewed by the other authors. All authors had full access to the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. PA is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.
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- Competing interests: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work. Specifically authors have no interest or investments in companies selling earplugs, headsets or greeting postcards.
- Ethical approval: This research has the ethical approval of the Institutional Review Board of the University hospital in Angers (NCT03355274).
- Data sharing: Anonymized trial data is available from the corresponding author.
- The manuscript's guarantor (PA) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

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Table 1: Inclusion and exclusion criteria for the study

Inclusion criteria	Exclusion criteria
Aged over 18 years old (no maximum age limit)	Pregnancy
Presence of positional forearm pain: (TOS suspected)	Prisoner or other kind of legal constraint
Absence of positional forearm pain: (controls)	Inability to understand the protocol
Coverage by the French National health care system	Ongoing participation in another clinical trial

Table 2 : Baseline characteristics of enrolled healthy participants and thoracic outlet syndrome (TOS) suspected patients. Values are numbers (percentages) or mean \pm standard deviation.

	TOS patients (n=32)	Controls (n=15)	p
Age (years)	37.6 \pm 10.0	28.0 \pm 14.0	.010
Male gender	9 (28%)	4 (27%)	1.00
Height (cm)	166 \pm 8	169 \pm 9	.312
Weight (kg)	70.0 \pm 17.2	58.6 \pm 9.5	.021
Right systolic blood pressure (mmHg)	125 \pm 13	120 \pm 12	.285
Right diastolic blood pressure (mmHg)	79 \pm 13	76 \pm 11	.360
Left systolic blood pressure (mmHg)	124 \pm 12	122 \pm 12	.666
Left diastolic blood pressure (mmHg)	79 \pm 11	78 \pm 11	.710
Ongoing treatment			
Statin or other cholesterol-lowering drugs	1 (3%)	1 (7%)	.541
Antihypertensive drugs	5 (16%)	1 (7%)	.648
Anticoagulants	1 (3%)	0	1.00
Antiplatelet agents	1 (3%)	1 (7%)	.541
Anti-contraceptive agent	3 (9%)	3 (20%)	.367
Cardiovascular risk factors			
hypertension	5 (16%)	1 (7%)	.648
diabetes mellitus	0	0	-
dyslipidemia	2 (6%)	1 (7%)	1.00
active smoker	12 (38%)	1 (7%)	.037
Upper limb trauma history			
chest or shoulder surgery	0	0	-
non-operated chest or shoulder trauma	3 (9%)	1 (7%)	1.00
non-operated arm or forearm fracture	3 (9%)	2 (13%)	.648

Table 3: Primary outcome: presence of forearm pain or discomfort during the call on each arm as a function of the presence or absence of arterial compression according to laboratory ultrasound investigations in TOS-suspected patients.

		Pain during the phone test			
		Negative	Left	Right	Bilateral
Ultrasound investigation result	Negative	3	3	2	0
	Left	2	1	0	1
	Right	1	0	1	3
	Bilateral	1	2	0	12

Figure 1: Transcutaneous oxygen recordings on the right (red line) and left (blue line) arm during the EAST maneuvers (gray squares) and while holding the telephone on the ear on the right (red square) and left (blue square) sides. As shown, patients A & B showed unilateral left arm ischemia on the EAST maneuvers but only patient B had left arm ischemia during the left phone test. Patients C & D have bilateral ischemia during the two EAST maneuvers and ischemia during the phone test although for the left side in patient C, the DROP value did not reach the -15 mmHg limit considered indicative for a significant positive result (blue dash line).

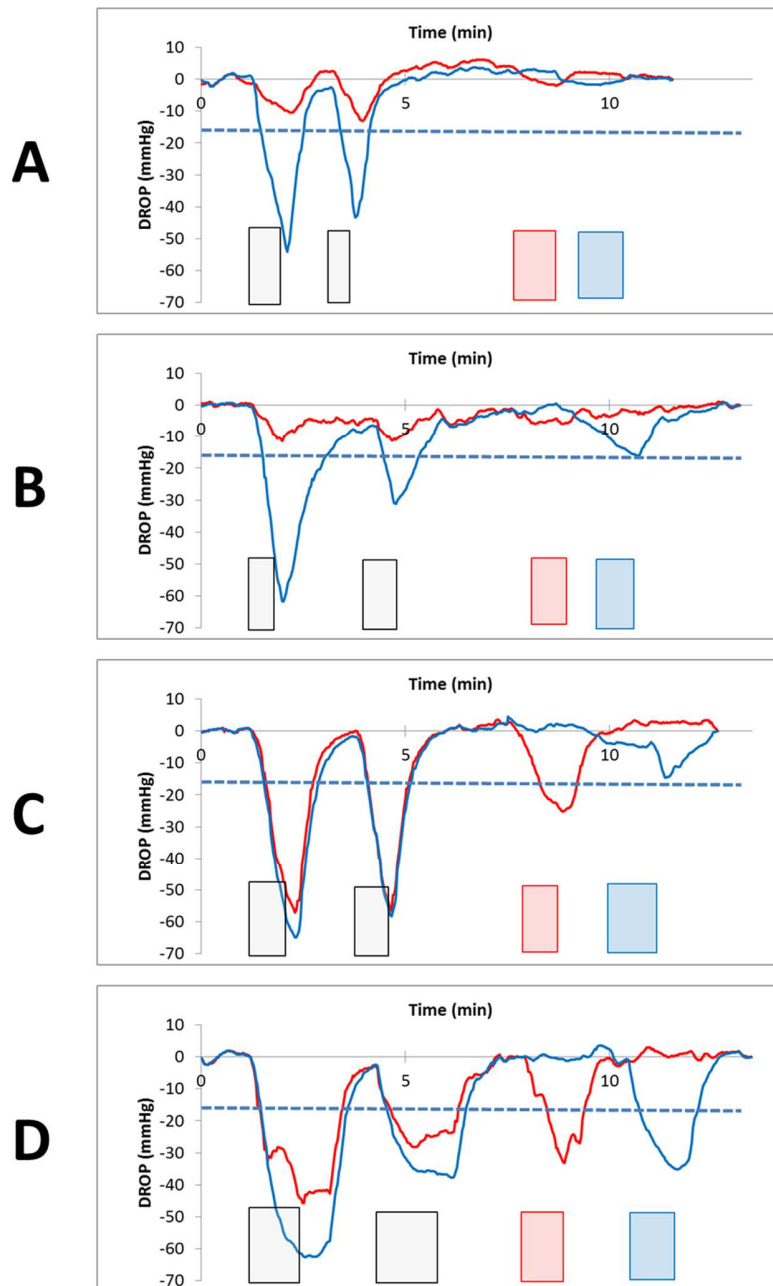


Figure 2: Minimal decrease from rest of oxygen pressure (DROPM) observed during the two EAST maneuvers and during the telephone test for all the 94 studied arms. The regression and coefficient of correlation are for all the results while the figure shows TOS-suspected patients and control subjects separately.

