ABSTRACT

Title: Therapeutic subclavian artery compression (TSAC) for peripheral vascular stasis.

Authors: Underwood, M., Powrie, D., Shaban, R. Z., McCann, A., Hsu, H. and Codd, C.A.

Objective: To establish the efficacy and safety of therapeutic subclavian artery compression (TSAC) for upper limb peripheral vascular stasis.

Methods: TSAC is a procedure to effect upper limb peripheral vascular stasis involving manual compression of the subclavian artery over the first rib. Using a cross-over design, the efficacy and safety of TSAC was tested on 20 clinically-screened, healthy adult volunteers under laboratory conditions. The participants were randomised to two intervention groups, and TSAC was tested by emergency physicians and advanced trainees under ultrasound-guided and non-ultrasound guided conditions. Successful peripheral vascular stasis was defined as a reduction of systolic BP of greater than 80% on the intervention arm. The criteria for safety included the absence of adverse effects within 24 hrs of the procedure, namely cerebrovascular accident, prolonged pain, neurological symptoms or ischaemia in the upper limb after the intervention.

Results: Peripheral vascular stasis was achieved in 113 (70.6%) of the total 160 TSAC attempts, and not in the remaining 47 (29.4%). The rates of success of peripheral vascular stasis were similar between ultrasound guided 58/80 (72.5%) and non-ultrasound guided 55/80 (68.5%) (p = 0.70). No adverse effects were observed by the research team or reported by any of the participants.

Conclusion: In this trial, TSAC for peripheral vascular stasis was demonstrated to be safe and effective in the laboratory setting. This technique has potential utility for controlling traumatic haemorrhage from proximal upper limb vascular injury that cannot otherwise be controlled to prevent mortality prior to definitive surgical management. Further research will investigate the utility of TSAC in both the pre-hospital and hospital setting for the management of proximal upper limb vascular injury.

INTRODUCTION

Trauma to the proximal upper limb vasculature can result in a devastating, potentially life-threatening injury. Within the general civilian population, it is relatively uncommon with an estimated incidence of 3-9% of all vascular injuries.[1, 2] However, in a recent wartime report from military operations in Iraq, injury of subclavian and axillary arteries represented 23% of all vascular injuries.[3]

Although the incidence is comparatively low, mortality from subclavian and axillary artery trauma is high. Two-thirds of people who sustain trauma to the upper limb proximal artery die from traumatic blood loss before reaching the hospital.[4] Of the remaining one-third of patients who reach the hospital alive, those who arrive hypotensive (systolic BP < 90mmHg) have a 57% mortality rate whilst those who are normotensive on arrival have a mortality rate of only 18%[5]. The overall hospital mortality rate has been reported between 34%[4] and 39%.[5] The differences in mortality will represent a number of factors including severity and pattern of injury, the difficulty of pre-hospital providers in controlling blood loss in this anatomically challenging area whilst expediting transport to definitive care, and lastly the availability of an appropriate vascular surgical service. It is widely acknowledged that the control of haemorrhage by emergency medical service providers in the pre-hospital care setting influences patient mortality associated with this type of trauma.[6]

Though widely acknowledged, there is little published data that examines the pre-hospital management of haemorrhage from these injuries. Techniques applicable to this setting include direct pressure over the wound,[7, 8] a fist placed in the axilla[9] and direct digital compression of the subclavian artery.[10] However, while references exist to the latter technique, literature searches have not identified any studies into its safety or effectiveness and it is not currently taught or utilised by local and military Emergency Medical System (EMS) providers.[11]

This study was designed to assess the efficacy and safety of a technique to affect peripheral vascular stasis and therefore improve survival rates. The technique is referred to as Therapeutic Subclavian Artery Compression (TSAC). It involves digital compression of the subclavian artery against the first rib just superior to the clavicle and lateral to the insertion point of the sternocleidomastoid muscle, after confirming that the subclavian is a safe distance from the carotid artery. The technique is best carried out with the operator standing behind the recumbent subject, and the thumb of the operator used to press down on the subclavian while the subject maintains their head in the neutral position. The key aims were to determine whether this relatively simple technique could be used to induce peripheral vascular stasis in laboratory conditions. If successful, such a procedure may have clinical application in the control arterial bleeding from the proximal upper limb.

METHODS

Literature Search

A systematic search of the literature guided this study. The following Medical Subject Heading (MeSH) terms were used: upper extremity; trauma; subclavian artery; vascular stasis; and exsanguination. The following computerized databases were searched: CINAHL™, MEDLINE™, PubMED™, EMBASE™ and the Cochrane Library™. The reference lists of all relevant articles were searched. The Australian Digital Thesis Program was included to search for any related theses. In addition, GoogleScholar™ was used to search for relevant articles. A restriction on this study is that only articles written in English were used and no publication date restrictions were applied to the search. Outcomes of searches are outlined in Appendix 1.

Study Design

This study was a two-phase, cross-over trial (Diagram 1) to determine the safety and efficacy of therapeutic subclavian artery compression (TSAC), as illustrated in Diagram 1. Cross-over or repeat-measures designs are experimental where one group of subjects is exposed to more than one condition or treatment in a random order. This design was chosen as it provides the highest advantage of ensuring the highest possible equivalence among subject exposed to difference conditions. Moreover, the strength of the cross-over design is that it decreases the potential influence of individual differences and increases variance control as all subjects serve as their own control [12]. This research design minimises covariate imbalance between the two groups, as each subject is their own control. Finally, this design enabled the study to occur within the limited financial resources available, yet providing for the three core features of experimental designs to be met—manipulation, randomization and control. The use of ultrasound guidance was used as the control while affording additional safety in this previously unstudied technique.

Setting

The study was undertaken in July 2011 in the Emergency Department at the Princess Alexandra Hospital, a level 6 tertiary referral centre in Queensland, Australia.

Research Ethics

Conduct of the study was approved by the Metro South (Princess Alexandra Hospital) and Griffith University Human Research Ethics Committees. The study was conducted in accordance with the approved protocol. There were no reported or observed adverse effects and no subjects withdrew from the study.

Outcome variable

Two outcome measures were established in this trial. The first outcome measure for efficacy was a manually-determined reduction in blood pressure of greater than 80% of the original systolic blood pressure. This was chosen because theoretically it would reduce the arterial pressure in the limb to below that of the arteriolar end of the capillary bed (35mmHg),[13] resulting in a clinically-significant vascular stasis.

The second outcome measure for safety was a verbal numerical pain scale used to assess the pain associated with this intervention. This scale was used to grade the level of pain prior, during and after the TSAC. The scale was chosen because of its reliability and ease of use[14]: 0 indicating no pain, 10 indicating severe pain. Research has supported that a verbal numeric pain scale is more reliable than a visual pain scale [15]. In addition to pain, other adverse events recorded included absence of cerebrovascular accidents, neurological symptoms or ischemia of the upper limb after the intervention.

Recruitment

Four volunteers were recruited to be the operators. They were randomised to two operator groups by the toss of a coin. Each of the two operator groups by chance consisted of one emergency physician and one final year advanced trainee in emergency medicine. The operators did not include the authors of this study.

Study participants were recruited by a research assistant. They were both males and females aged between 18 and 65 years. Informed written consent was obtained from participants prior to their participation. Allocation to Study Participant Group 1 or Study Participant Group 2 was determined by a toss of a coin.

Screening (Inclusion / Exclusion)

The inclusion criteria were health, consenting adults. Study participants were screened by a specialist vascular physician, who sourced a detailed vascular medicine history, physical examination, and ultrasound assessment of their subclavian arteries. The exclusion criteria described in Table 1 were applied. The demographics of the participants collected were gender, height and weight.

Phase 1

The aim of the Phase 1 was to determine the efficacy and safety of TSAC using static ultrasound guidance for inducing peripheral vascular stasis. Skin markings were used to define the location of the subclavian artery (Photograph 1). Each operator group then performed a single attempt of TSAC on both the right and left subclavian arteries in each study participant of their assigned group (Photograph 2). Peripheral vascular flow was then measured during the intervention using a manual sphygmomanometer (to determine blood pressure). This measurement was taken and recorded by qualified critical care nurses who did not undergo specific training for this study prior to their involvement.

Phase 2

In Phase 2, the efficacy and safety of non-ultrasound guided TSAC for inducing peripheral vascular stasis. There was a time delay of at least one hour between phase one and phase two. The surface marking was removed and the study participant groups then crossed-over with respect to operator groups. This ensured that the operator was now performing the technique on a study participant they had not performed the technique on in Phase 1, to minimise operator learning effect. The intervention was then performed again on each subclavian artery in the study participant groups without ultrasound guidance using blood pressure and palpation of the radial pulse to determine peripheral flow. (Diagram 1)

In total, the cross over design allowed for a total of 160 TSAC attempts.

Statistical analysis

Data was recorded on data sheets by research assistants. It was then collated in Microsoft Excel™. Statistical analysis was undertaken by a biostatistician using Statistical Analysis Software™ Version 9.3. Each of the 20 participants experienced each of the unguided and guided procedures 4 times (2 operators x 2 sides), for a total of 160 observations in all. Power calculations were based on the difference between the average success rate (over all 20 participants, each with a set of 4 observations) for guided and unguided procedures. Assuming a correlation of 0.5 between success rates within the same participant, the study would have 80% and 90% power to detect a difference of at least 16% and 19%, respectively, between the success rates of guided vs. unguided procedures (two-sided test, 5% level of significance). A difference of greater than 20% in success rates between guided and unguided would lead to a recommendation that the procedure should be undertaken with ultrasound guidance despite logistical problems in implementing this.

Demographic data was expressed as a median, inter-quartile range and range. Success at >80% reduction in systolic blood pressure was expressed as a proportion and analysed using chi squared analysis. Statistical reliability was also analysed with this method. A p value of <0.05 was considered significant.

RESULTS

Demographics

Twenty subjects were enrolled, 9 (45%) males and 11 (55%) females. Their ages ranged from 28 to 63 years, with a median of 34 years (IQR 29-36 range 28-63 years). The median height was 172 cm (IQR 169- 177; range 156-190 cm) and the median weight was 79kg (IQR 69-89; range 59-154kg). The median BMI was 26 (IQR 23-29; range 21-42). No study participant withdrew from the study.

Primary outcome measures:

In this study, TSAC was effective at achieving peripheral vascular stasis. In the non-ultrasound guided group, 55/80 (69%) of interventions achieved success for greater than 80% reduction in systolic blood pressure. In the ultrasound-guide group, 58/80 (73 %) achieved success for systolic blood pressure reduction. Therefore, the success rates of peripheral vascular stasis were similar between ultrasound guided and non-ultrasound guided TSAC.

The observed difference in success rates was not statistically significant ($p = 0.70$), which demonstrated that there is no statistically significant difference between the ultrasound guided and non-ultrasound guided TSAC.

Using a verbal numerical pain scale (0 = no pain and 10= worst possible), approximately one-fifth (19%, n=31) of test subjects reported no pain and the majority reported a pain score of less than five (71%, n=115). Only 8% (n=13) of subjects had pain scores above six. Only one participant reported paraesthesia in the upper limb during phase 1 which spontaneously resolved by phase 2.

The statistical reliability of the cross-over study design and thus validity of the overall treatment effect (systolic blood pressure) was determined (Chi-squared test p=0.99).

DISCUSSION

Proximal upper limb vascular trauma continues to have high mortality rates in both civilian and military populations despite the development of increasingly sophisticated endovascular and anastomotic repair techniques. [3,4,8] Intra-operative and post-operative mortality rates are low[1,8] which demonstrates that pre-hospital and emergency department management of haemorrhage remains critical to determining survival.

The aim of this study was to define the efficacy and safety of a technique called Therapeutic Subclavian Artery Compression (TSAC) whereby compression of the subclavian artery was attempted against the first rib in order to achieve peripheral blood flow stasis. In this trial, operators successfully induced peripheral vascular stasis using TSAC in the majority (69-73%) of the attempts of TSAC. The rates of peripheral vascular stasis were not statistically significant between ultrasound guided and non-ultrasound guided techniques thereby demonstrating that delineation of the anatomy by ultrasound was not necessary to ensure direct compression. This is an important finding as ultrasound may not be available in the pre-hospital setting nor achievable in the haemorrhaging patient. Moreover, it is not routinely used in the management of haemorrhage. Only one participant experienced paraesthesia to the upper limb in phase one that resolved spontaneously.

We believe that this technique may have application in the pre-hospital and emergency department environment as a stabilising technique whilst allowing concurrent assembly of appropriately skilled surgeons, anaesthetists and theatre staff. The results of this study demonstrate the reduction of peripheral vascular blood flow indicated by the reduction of BP by greater than 80%, can be achieved by direct pressure over a readily accessible site. A reduction of BP to >80% of original systolic pressure was determined prior to the study. It is known that pressure at the arteriolar end of the capillary bed is approximately 35mmHg. For example if a normal systolic BP is considered 120mmHg then an 80% reduction would result in a pressure of approximately 24mmHg. This is less than normal pressure at this point and any arteriolar bleeding would likely be controlled.

Many patients who suffer proximal upper limb vascular injury do not survive to emergency department admission. In a South African study[7] 228 patients were seen at a hospital in Johannesburg with subclavian artery injuries. Almost two-thirds (61%) were certified dead on arrival and in the 39% that did reach hospital, 72% were in shock and 22% had an unrecordable blood pressure. The pre-hospital mortality rate for subclavian injury has been estimated through forensic pathology autopsy data[8] and shown that 74% of patients die from subclavian artery trauma prior to reaching hospital. It is acknowledged that emergency medical services control of haemorrhage (other pre-hospital issues notwithstanding) significantly contributes to improve the survival of patients with this type of trauma as the primary determinant of survival to hospital. The important predictor of survivability includes the haemodynamic status of the patient on arrival to the emergency department. Those that arrive with haemodynamic stability have far better mortality outcomes compared to those who arrive unstable.[5]

Literature searches have not identified any rigorous testing of first aide techniques for proximal upper limb vascular trauma. Our study was limited to a laboratory setting using healthy volunteers. Whilst participants were young and representative of the population who sustain these types of injuries[1, 5, 9, 16] they were in a controlled environment with no evidence of massive haemorrhage which could influence the performance of operators. Height, weight or BMI of both operators and participants could determine the success rate of the technique. Larger operators reported they found the technique easier, and it was generally considered amongst all operators to be easier to perform the technique in smaller patients. However, his study was not designed to formally investigate this.

The operators, whilst experienced in emergency medicine and the anatomy of the region, were given only brief training in the technique by one of the investigators. This may have influenced their ability to perform the manoeuvre; however, the primary objective of the study was not to examine operator ability or learning. It was designed to evaluate the potential of a simple, non-invasive technique that may reduce blood flow in exsanguinating trauma in the "in vitro" environment. The two participant groups were considered comparable in demographics. The cross-over design and two- phase trial allowed participants to serve as their own controls and increased the power of the study by effectively demonstrating 160 TSACs

Future studies should be undertaken to optimise the technique, instruct EMS providers and attempt to apply these findings to a setting that closely represents a realistic clinical situation. Discussions with Queensland Ambulance Service and military medical service providers are currently being undertaken about the potential for a collaborative investigation of the technique, including teaching studies and studies into effectiveness. It is hoped that TSAC will successfully improve outcomes for patients who sustain traumatic haemorrhage from proximal upper limb vascular trauma.

CONCLUSION

TSAC appears to be a safe and efficacious method of obtaining peripheral vascular stasis in the upper limb. This may have a role in controlling exsanguination from proximal upper limb vascular trauma.

Declaration

Catrina Codd was previously employed as the Research Manager for the Queensland Emergency Medicine Research Foundation however was not involved with allocation of funding for this study grant and has no commercial interest with this study. Other authors report no conflict of interest in this paper. Funding for this research was provided by the Queensland Emergency Medicine Research Foundation.

The authors would like to thank Dr Peter Moran for describing the technique of TSAC. The authors would also like to thank Drs Colin Page and Ogilvie Thom for their review of the manuscript.

REFERENCES

1. Gill H, S. E, Bekker W, Nicol AJ, Navasaria PH. Civilian penetrating axillary artery injuries. World Journal of Surgery 2011;35:962-66.
2. Graham JM, Mattox KL, Felicano DV, DeBakeru ME. Vascular Injuries of the Axilla. Annals of Surgery 1982;195:232-38.
3. Clouse D, Rasmussen TE, Perlstein J, Sutherland MJ, Peck MA, Eliason JL, et al. Upper extremity vascular injury: a current in-teather wartime report from operation Iraqi Freedom. Annals of Vascular Surgery 2006;20:429-36.
4. Demetriades D, Chahwan S, Gomez H, Peng R, Velmahos G, Murray J, et al. Penetrating injuries to the subclavian and axillary vessels. Jounal of the American College of Surgeons 1999;188(290-95).
5. Lin PH, Koffron AJ, Guske PJ, Lujan HJ, Heilizer TJ, Yario RF, et al. Penetrating injuries to the subclavian artery. The American Journal of Surgery 2003;185:580-84.
6. Modrall G, Weaver F, Yellin AE. Diagnosis and management of penetrating vascular trauma in the injured extremity. Emergency Clinics of North America 1998;16:129-44.
7. Demetriades D, Rabinowitz B, Pezikis A, Franklin J, Palexas G. Subclavian vascular injuries. British Journal of Surgery 1987;744:1001-03.
8. McKinley AG, Abdool Carrim ATO, Robbs JV. Management of proximal axillary and subclavian artery injuries. British Journal of Surgery 2000;87:79-85.
9. Degiannis E, Levy RD, Potokar T, Saadia R. Penetrating injuries of the axillary artery. Australian and New Zealand Journal of Surgery 1995;65:327-30.
10. Moore KL, Dalley AF, Agur AM. Clinically oriented anatomy. 6th ed. Boston, USA: Lipponcott, Williams and Wilkins; 1999.
11. Adjunct Associate Professor Lieutenant Colonel David Ward. Associate Professor in Public Health, Queensland University of Technology & Australian Army, Commonwealth of Australia. Personal Communiction, Brisbane, Qld, Australia; 2011.

12. Polit DF, Hungler BP. Nursing research: principles and procedures. Philadelphia: Lippincott, Williams & Wilkins; 1999.

13. Barrett KE, Barman SM, Boitano S, Brooks H. Blood as a Circulatory Fluid & the Dynamics of Blood & Lymph Flow. In: Barrett KE, Barman SM, Boitano S, Brooks H, editors. Ganong's Review of Medical Physiology: McGraw Hill; 2011.

14. Costello P, Wiseman J, Douglas I, Batten B, Bennett M. Assessing hospice inpatients with pain using numerical rating scales. Palliative Medicine 2001;15(3):257-58.

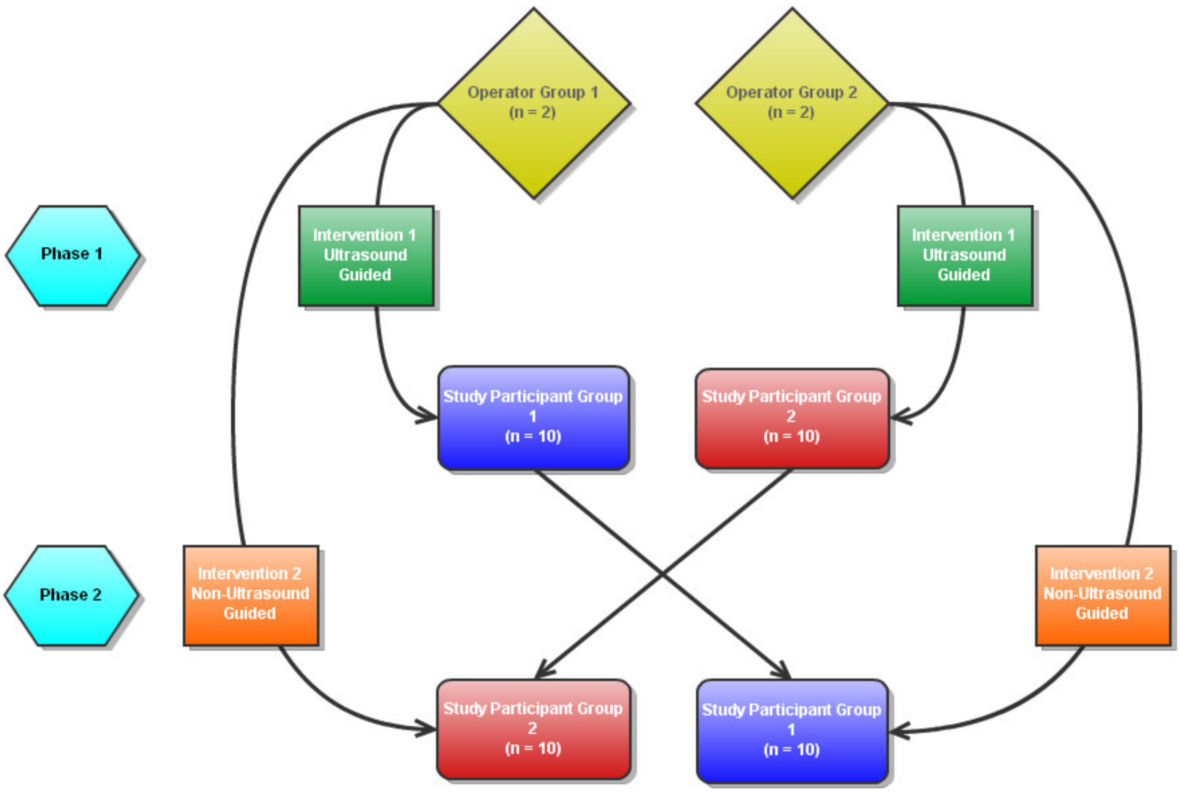
15. Mawdsley RH, Moran KA, Conniff LA. Reliability of two commonly used pain scales with elderly patients. Journal of Geriatric Physical Therapy 2002;24(3):25.

16. Franz RW, Goodwin RB, Hartmann JF, Wright ML. Manamgent of upper extremity arterial injuries at an urban level 1 trauma centre. Annals of Vascular Surgery 2009;23:8-16.

TABLE 1 - Screening tool

	Screening question	Exclusion criteria
History	Vascular disease including Raynaud's phenomenon	Confirmed or suspected
Examination	Blood pressure	SBP > 200 mmHg DBP > 100 mmHg
	Peripheral pulse	Abnormal
	Bruits	Present
	Pemberton's sign	Present
	Modified Pemberton's (Adson's manouvre)	Present
Investigation	Bilateral proximal upper limb vascular ultrasound	Local disease
		Abnormal anatomy
		Close proximity to the carotid artery

DIAGRAM 1 - Study design



PHOTOGRAPH 1 – Marking the subclavian artery

PHOTOGRAPH 2 – Performing TSAC

Appendix 1 – Literature Search and Table of Hits/Relevant Hits:

The following databases were searched: Medline, CINAHL (Cumulative Index to Nursing and Allied Health Literature), EMBASE and Cochrane.

Hand searching of references from relevant articles was also used.

Reference texts and personal communication with a medical officer within the Australian Defence Force (Associate Professor Lieutenant Colonel David Ward) were also ultilised.

The following search strategies were employed:

Date Searched	Database	Search strategy	Title/abstract reviewed	Relevant and not duplicated articles retrieved
April 2010	Medline (Ovid)	Upper extremity AND vascular AND injury	159	1
		Subclavian artery AND penetrating AND trauma	63	2
		Upper extremity AND vascular AND trauma	142	1
July 2010	Medline (Ovid)	Axillary artery AND penetrating AND trauma	37	1
		Vascular AND injury AND axilla	25	1
		Subclavian artery AND penetrating AND injury	67	3
January 2011	CINAHL (Ovid)	Pain scales AND numerical	287	2
January 2011	EMBASE	Upper extremity AND vascular AND injury AND penetrating	21	1
January 2011	Cochrane	Upper extremity AND vascular AND injury	2	0