COMPARISON OF FOUR ROUTES OF CENTRAL VEIN CANNULATION USING REAL TIME ULTRASOUND GUIDANCE IN CARDIOVASCULAR SURGICAL PATIENTS – A PROSPECTIVE RANDOMISED STUDY

THESIS PROJECT

BY

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DECLARATION

I hereby declare that this thesis entitled **"COMPARISON OF FOUR ROUTES OF CENTRAL VEIN CANNULATION USING REAL TIME ULTRASOUND GUIDANCE IN CARDIOVASCULAR SURGICAL PATIENTS –A PROSPECTIVE RANDOMISED STUDY"** has been prepared by me under the able guidance of Professor Prasanta Kumar Dash, Division Of Cardiothoracic And Vascular Anaesthesia, Department Of Anaesthesiology, at Sree Chitra Tirunal Institute For Medical Sciences & Technology, Thiruvananthapuram.

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CONTENTS

INTRODUCTION

INTRODUCTION

Central venous catheterization is an integral part of invasive monitoring and management in the modern era. They are inserted by anesthesiologists, intensivists, radiologists and attending physicians. The first description of central venous access was given by ***Aubaniac***[1]**,** in which he described the use of subclavian access while resuscitating trauma victims in the battlefield. Seldinger modified the method of venous catheterization and introduced the catheter over guidewire technique which is followed world over nowadays. Various other routes were described later on for central venous access.

Yoffa[2] introduced the use of supraclavicular subclavian route for central venous catheterization in 1965 and demonstrated its ease of access and high success rates. The internal jugular route for central venous access has been described as early as in 1966 by ***Hermosura***[3] and co-workers. Later on other routes of venous access were described which included axillary & femoral vein. Each route is associated with its own set of complications and the overall incidence rate of mechanical complications ranges from 5-19%[4,5,6] as described in literature. The choice of the access site depends on various factors including physician preference, ease of access, coagulation status, probable duration of catheter stay, infection rates and complication rates.

Complications of central venous catheterization include arterial puncture, hematoma, hemothorax, pneumothorax, arterial-venous fistula, air embolism, nerve injury, infections and thrombosis. The incidence of complications differs in various routes and this has been well studied and published in literature. In general, incidence of mechanical complications are reported to be higher with femoral route when compared to jugular or subclavian route. The jugular venous access has a higher incidence of arterial puncture than subclavian route while subclavian route has the highest incidence of pneumothorax[7,8].

The commonest complication of central venous access is accidental arterial puncture and hematoma since the neurovascular bundle which carries the vein always contains an artery, making it prone for injury during a blind procedure. This adds significantly to morbidity, cost of hospitalization and even mortality when injuries are serious enough requiring interventions like surgical exploration or insertion of chest drains. These complications can be more severe in patients, who have low platelet count, on antiplatelet medications, on anticoagulants or patients with bleeding diathesis. There are reports of devastating complications including accidental puncture of pulmonary arteries[9]or pericardial tamponade during central venous catheterization[10]. Any serious complication including infections of central venous catheter adds a substantial amount to the cost of treatment making it a priority to minimize the incidence of any complications.

Pneumothorax is another common mechanical complication of central venous access. The incidence of pneumothorax described in literature is around 1 to 6%[11]. Treatment of pneumothorax depends on the severity and rate of progression, from careful follow up to insertion of chest drain. In perioperative period, when the patient is mechanically ventilated, the presentation can be immediate and prompt treatment with chest drain insertion may be needed. Methods to minimize this complication include choosing alternate route of central venous access, limiting the number of needle passes, attempt by an experienced operator and use of ultrasound guidance. When using ultrasound guidance, long axis view keeps the whole length of needle in viewwhich prevents inadvertent pleural puncture.

Catheter related blood stream infection is another serious complication of central venous catheterization and the factors affecting the infection rate include emergency insertion, type of central line (eg ; antibiotic / silver impregnated), duration of catheter stay, route of insertion among others. Infectious complications are reported to lie in the range of 5 to 26%[5]Femoral venous catheterization is proven to have the maximum incidence of infections and subclavian the least. This is more so when the duration of catheter stay is prolonged. The consistent evidence of increased infections with femoral route has prompted the clinicians to avoid this route whenever possible.

The infraclavicular subclavian and internal jugular vein were the two routes classically described for upper body central venous access. Later on it was demonstrated that axillary vein can be catheterized safely with decreased chances of pneumothorax. The usefulness of ultrasound was demonstrated in case of infraclavicular axillary vein catheterization with low incidence of complications including pneumothorax.

Supraclavicular approach to subclavian vein is a technique with high success rate and safety record. Even though the technique was described as early as 1965 the technique fell out of use for reasons unknown. There is a renewed interest in the use of these techniques and studies have come up with good safety record with respect to mechanical complications. This route also has the added advantage of improved patient comfort and ease of nursing care when compared to jugular route. Use of ultrasound was studied in supraclavicular route and has high catheterization success rates.

Ultrasound in medicine

Ultrasonic rays were discovered in 1883 even years before X-rays were discovered. The initial application of ultrasound was in First World War and were used to detect the submarines. The use of ultrasound in medical practice started off in the field of obstetrics and later on was adopted in various other fields including abdominal, cardiac and pelvic diagnostics. The use of ultrasound in anesthesia and intensive care ranges from guidance in regional anesthesia and vascular access to detecting complications like pneumothorax or hemothorax and as a part of emergency screening in trauma (Focused Abdominal Sonography in Trauma- FAST)[12].

Ultrasonographic guidance in central venous access has converted a blind procedure into a ‘procedure under vision’ reducing the complication rates markedly. Many studies have come up using ultrasonography (USG) guidance for central venous access demonstrating a decrease in incidence of complications, decreased number of needle passes and higher success rates. Although there are studies and reports of use of USG guidance in all routes of central line access like subclavian, axillary and femoral routes, the highest evidence of usefulness has been demonstrated in internal jugular route. The huge body of evidence demonstrating the safety and efficacy of ultrasound in jugular vein cannulation has led to the incorporation of ultrasound usein NICE GUIDELINES[13] for safe practices.

USG guidance was thought to be difficult for infraclavicular subclavian vein access due to the presence of clavicle obscuring the view. The older studies could not clearly establish the efficacy of USG in infraclavicular route. However more recent studies has shown that subclavian vein can be visualized with ultrasound and venous access can be undertaken with fewer needle passes and lesser complication rates when compared to classical landmark technique. The body of evidence in subclavian vein cannulation is growing and in view of this emerging evidences, French society of Anesthesia [Socie´te´ franc ¸ aised’anesthe´sie et de re´animation (SFAR)][14] has recommended the use of ultrasound for subclavian vein access.

Central venous access in Cardiac Surgery

Central venous access is an integral part in cardiac anesthesia and serves both monitoring as well as therapeutic purposes (infusion of vasoactive agents and other irritant drugs). The best route for central venous access in these patients is not clearly established. Internal jugular and Infraclavicular subclavian are the most commonly used routes in cardiac surgery. The concerns of serious mechanical complications like hemothorax which can go undetected and produce devastating consequences after full heparinisation, pneumothorax, and concerns of catheter malfunction due to sternal retraction has waned the enthusiasm in subclavian access for cardiac surgeries. The availability and expertise in the use of ultrasound for jugular vein cannulation has grown, making it a safer alternative to subclavian venous access. Use of Supraclavicular subclavian access has been reported in recent literature in cardiac surgeries and gives positive results. The use of axillary vein has not been reported in cardiac surgeries.

We postulate that with the use of ultrasound if the incidence of serious mechanical complications can be avoided or minimized, the alternative routes of central venous access can be a substitute or replacement for internal jugular vein in cardiovascular surgical patients.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Millions of central vein catheterization are done annually by various clinicians for monitoring as well as therapeutic purposes. Central lines insertion was first described by ***Aubaniac***[1] in 1952 when he inserted a needle in subclavian vein under the clavicle. Various other routes of central venous access were described subsequently in the next decade including the infraclavicular axillary vein approach, jugular venous route and supraclavicular approach to subclavian vein. Soon after the description of subclavian insertion by Aubaniac, in the following year ***Seldinger***[15] modified the technique of catheter insertion by passing a guide wire through the needle and threading the catheter over the guide wire. This technique became popular worldwide and now goes by the name ‘Seldinger Technique’.

Yoffa[2]in 1965 described supraclavicular subclavian vein catheterization where he described various landmarks and the technique of cannulation. Several modifications of this technique[16] with small changes in the needle insertion point or angulation has been described subsequently.

Hermosura and co-workers[3] first described the technique of percutaneous internal jugular vein (IJV) cannulation in 1966. ***Nickalls***[17] described the infraclavicular approach to axillary vein cannulation in 1985. He described two surface landmarks for axillary vein cannulation, first one being three finger breadth below coracoid process and the second point as the junction of medial one third and lateral two third of clavicle. The puncture was in this line at the medial border of pectoralis minor. He postulated that the axillary vein being away from the thoracic inlet the incidence of pneumothorax will be lower than with subclavian vein catheterization.

Central venous catheterization is associated with many complications of which some can be serious and some life threatening. They are broadly classified into infectious, mechanical, and thrombotic complications. The incidence and associations of these complications with different approaches for central venous catheterization have been reported in literature.

MECHANICAL COMPLICATIONS & PREVENTIVE STRATEGIES

Mechanical complications include pneumothorax, hemothorax, accidental arterial puncture, hematoma, nerve injury, chylothorax(left side) and air embolism. Although many of these complications are innocuous and self limiting some can be serious needing active interventions like blood transfusion or insertion of a chest drain and some can even be life threatening.

Strategies to minimize mechanical complications of central venous catheterization include proper knowledge of the anatomy, insertion by an experienced physician, limiting the number of attempts, proper selection of the route of central venous access, and use of ultrasound guidance.

Tsotsolos etal[11] also shared the same opinion on experience of the clinician in performing the procedure as a major risk factor for mechanical complications.

However, ***Schummer et al***[18] has studied central venous cannulation by landmark technique through various routes and reported a high incidence of mechanical complications even with experienced operators. He reported a significantly higher incidence of arterial puncture with IJV cannulation when compared with subclavian vein cannulation. A thorough knowledge of the anatomy of the intended structure is needed to minimize the complications.

Another modifiable factor which can decrease the number of complications is the knowledge of proper anatomy of the vein. Anatomic considerations while inserting central line through various routes have been described in detail by ***Bannon et al***[19]. In his article he described the anatomy of the central veins commonly used for catheterization, proper preparation, insertion techniques, various complications and use of ultrasound guidance. He concluded that even in the era of ultrasound where the vein is cannulated directly under vision, the knowledge of anatomy of the intended vessel and its surrounding structures is crucial in minimizing the complications and improving success rates.

The next factor in determining the incidence of mechanical complications is the choice of the route for venous access. When all mechanical complications are considered together, the maximum incidence of complications are seen with femoral catheterization which predominantly are arterial punctures and hematoma[5].

Merrer et al[8] in his study comparing the complications of femoral venous access and subclavian approach in critically ill patients reported infection rates of 19.8% in femoral venous catheterization compared to 4.5% with subclavian route. The incidence of thrombosis was also higher with femoral route. The mechanical complications were similar in the two groups.

The high incidence of thrombotic complications along with the high rates of infection has made femoral route the least preferred route for central venous access except in emergencies[20,21,22].

Pneumothorax is one of the most common mechanical complication that can occur during insertion. It represents around 30% of the total mechanical complications of central line insertion. The reported incidence of pneumothorax in literature is between 1- 6.6%[11] with higher incidences in situations like emergency insertions, larger catheter use (dialysis) and increased number of needle passes.

Eisen et al[4] in a retrospective study of mechanical complications in central venous catheters, observed a pneumothorax incidence of 2.3% with subclavian route whereas there was none in the jugular vein group. The catheter insertion was attempted by even residents and interns under supervision. They concluded that the incidence of complications are higher with subclavian route and this is to be considered while choosing the approach. They also suggested to limit the number of attempts to 2in order to minimize complications.

When serious mechanical complications are considered i.e. hematoma or hemothorax requiring blood transfusion or exploration, and pneumothorax requiring drainage, the incidence is more with subclavian vein catheterization than all other routes. Catheter malposition although not a serious complication may hinder proper monitoring of central venous pressure (CVP). The ideal position of the tip of an upper body venous catheter is within 2cm of superior vena cava (SVC)- right atrium (RA) junction or in the upper RA. The incidence of catheter malposition ranges form 1-4%[18,23,24] more with infraclavicular subclavian approach.

Infections in central line insertion is associated with a lot of factors including emergency insertion, length of catheter stay, type of catheter, site of insertion and the age of the patient. The use of femoral route is associated with highest rates of infection and subclavian vein the least. A study by ***Merrer et al***[8] comparing the femoral and subclavian venous route in critically ill patients reported a significantly lower incidence of infections (4.5 infections per thousand catheter days when compared to 1.2 infections per thousand catheter days) with subclavian route. A randomized trial found that subclavian venouscatheterization was associated with a significantly lower rate of total infectious complications than femoral venous catheterization and a trend toward a lower rate of suspected or confirmed catheter-related bloodstream infections (1.2 infections per 1000catheter-days, vs. 4.5 infections per 1000 with femoral catheterization; P=0.07). Available evidence suggests that subclavian catheterization is less likely to result in catheter-related infection than internal jugular catheterization, although the two approaches have not been compared in randomized trials[25,26,27].In his article on preventing complications associated with central venous access ***McGee et al***[5] also suggest the use of subclavian vein cannulation as one of the measures to minimize catheter related infections.

Thrombotic complications are least associated with subclavian vein catheterization.

Life threatening complications of central line insertion although rare have been reported in literature which ranges from malignant arrhythmias to accidental puncture of great vessels.

Moriceau et al[9] reported a case of accidental pulmonary artery injury on attempted subclavian vein catheterization. He attributed the cause of the accident to the relative inexperience of the user and suggested experienced clinicians performing or supervising the procedure.

Ultrasound for Vascular access

Ultrasound imaging uses high frequency (2- 10 MHz) sound waves generated by probes using the piezoelectric effect. This enables the probe to transmit and receive sound waves. Reflection of sound waves occurs at interfaces between tissues of different impedance and is shown in the ultrasound image as a bright echo. Fluid such as blood in vessels is black because near complete transmission of ultrasound occurs. Bone and air cause marked reflection, appearing white in B-mode images. This strong reflection creates an acoustic shadow which means structures beyond these tissuescannot be seen. Conveniently, most large vessels that are catheterized can be imaged with an ultrasound probe. Arteries are easily identifiable as they pulsate and are difficult to compress with probe. Veins are non-pulsatile, easily compressible, and distend when the patient is placed in a head down position or when the Valsalva maneuver is performed. Real time images are much easier to interpret than still images because of these dynamic findings. The effects of various patient positions on great vessels in the neck have been documented using ultrasound.

The occurrence of a serious mechanical complications adds significantly to the morbidity and mortality of the patient and adds considerably to the cost of treatment. This makes the addition of any preventive strategy imperative in these procedures. No other intervention or method has decreased the incidence of these complications in vascular access as ultrasound guidance. There is a huge body of literature demonstrating the usefulness of ultrasound in vascular access. The decreased incidence of mechanical complications like accidental arterial puncture, hematoma or pneumothorax with the use of ultrasound has been shown in various studies,[28],[29],[30].

Ultrasound guidance was first used for vascular access in 1984 by ***Legler et al***[31]. He compared the use of Doppler pre-location to classic landmark technique to guide the venous cannulation. He demonstrated the need of lesser needle passes and higher success rates with Doppler pre-location. Later on, real time guidance for visualizing the vein and catheterization superseded the use of Doppler guided vascular access. In fact, the NICE guidelines says that audio guided Doppler ultrasound guidance is not recommended for CVC insertions.

Denys et al[32] in one of the earlier studies comparing ultrasound guidance and external landmark technique for IJV cannulation reported success rate of 100% using ultrasound and 88.1% using the landmark-guided technique ($p<0.001$). The first attempt success rates were also significantly higher in the USG group ($p<0.001$). Average access time (skin to vein) was also significantly shorter with ultrasound approach when compared to landmark approach ($p<0.001$). The incidence of arterial puncture was 8.3% in the landmark group compared to 1.3% in USG guided group which also was statistically significant.

Fathi et al[28] in a more recent study compared anatomical landmark and USG guided internal jugular vein catheterization in patients undergoing cardiac surgery. He reported high success rates of 99.4% with USG guidance. They found a significantly less number of carotid artery puncture with ultrasound guidance compared to landmark technique.

Slama and co–workers (1997)[30] in a prospective randomized study, compareduse of anatomical landmarks with use of ultrasound guidancefor IJV cannulationby junior house staff. They found that IJV cannulation was successful in 100% patients in the ultrasound group and 76% in the control group (p < 0.01). Average access time was longer in the control group (235 ± 408 s vs. 95 ± 174 s, p = 0.06) and carotid artery puncture occurred in five patients in each group. Jugular cannulation was successful at first attempt in 26% in the control group and 43% in the ultrasound group (p = 0.11). 86% in the ultrasound group and 55% in the control group were cannulated within 3 min. Hence Ultrasound guidance improved the success rate of IJV cannulation and should be used when successful cannulation by the external landmark-guided technique is not achieved within 3 minutes.

Verghese and co-workers (1999)[33] studied 95 infants, comparing ultrasound guided IJV cannulation with traditional landmark method. They found that, the success rate was 100%in the ultrasound group, with no carotid artery punctures, and 77% in the landmark's group, with a *25%*incidence of carotid artery punctures. Both differences were significant ***(P <0.0004).*** The cannulation time was less, the number of attempts were fewer, and the failure rate was significantly lower in the ultrasound group than in the landmark group (median cannulation time 4.2 min versus 14 min ; median number of attempts 1.3 versus 3.3). He concluded that ultrasonographic localization of the IJV was superior to the landmark's technique in terms of overall success, speed, and decreased incidence of carotid artery puncture.

Mansfield et al[34] compared subclavian vein catheterization with and without ultrasound guidance and found no effect of USG in decreasing the complications or failures. He concluded that the USG guidance is of no use in subclavian vein cannulations. However this study was one of the earlier studies when USG guidance was developing, and the ultrasound was used for pre-location alone and not for real time guidance.

Ultrasound guidance has shown to decrease the venous access time, number of needle passes and the incidence of mechanical complications, improves overall and first attempt success rates. The evidence of the efficacy and usefulness of ultrasound in internal jugular vein cannulation is strong and this has prompted the adoption of ultrasound guidance in NICE guidelines for safe practices in 2002.

The subclavian vein was classically thought to be inaccessible to ultrasound access due to the presence of clavicle obscuring the view. There were conflicting evidences in literature for the efficacy of ultrasound in infraclavicular subclavian vein catheterization in 2002 when NICE guidelines were published. However, there is growing body of evidence showing the safety and efficacy of ultrasound guidance in preventing mechanical complications and improving the success rates in subclavian vein cannulation. ***Gualtieri et al***[35] in his study demonstrated a higher success rates of subclavian cannulation with ultrasound guidance even with inexperienced operators.

Brass et al[36] in a Cochrane database review on ultrasound guidance versus landmark methods for subclavian and femoral vein catheterizations found that the quality of evidence was very low or low for comparing these routes due to the fewer number of proper trials. However the analyses of available data suggest that two-dimensional ultrasound improves some, but not all, aspects of the effectiveness and safety of central venous catheter insertion. They observed a decrease incidence of reported arterial puncture and hematoma with the use of ultrasound and no added advantage with respect to other parameters like success rates, number of attempts or time taken for cannulations.

National Institute for Clinical Excellence [NICE] guidelines[13] has proposed the following recommendations after reviewing pooled data from various RCTs comparing landmark method with USG guided cannulation (Guidance Number - 49).

1 Two-dimensional (2-D) imaging ultrasound guidance is recommended as the preferred method for insertion of central venous catheters (CVCs) into the internal jugular vein (IJV) in adults and children in elective situations.

2. The use of two-dimensional (2-D) imaging ultrasound guidance should be considered in most clinical circumstances where CVC insertion is necessary either electively or in an emergency situation.

3. It is recommended that all those involved in placing CVCs using two-dimensional (2-D) imaging ultrasound guidance should undertake appropriate training to achieve competence.

4. Audio-guided Doppler ultrasound guidance is not recommended for CVC insertion. The committee agreed on the fact that the evidence for Internal jugular was robust when compared to other routes and the recommendation for routes other than IJV is an extrapolation from those results.

Board of the French Society of Anaesthesia and Intensive Care [Socie´te´ francaised'anesthesie et de re´animation (SFAR)][14] came up with similar guidelines for the use of ultrasound in vascular access. After studying various RCTs showing the advantages of USG in IJV approach they strongly recommended that ultrasound-guided puncture be used rather than anatomical cutaneous landmark-based cannulation to insert venous access catheters in internal jugular vein in adults.

After analyzing 3 RCTs, they found a significant decrease in the number of arterial punctures, hematomas, pneumothorax and hemothorax with the use of ultrasound guidance. After reviewing all the data available they strongly recommended that ultrasound-guided puncture be used rather than anatomical landmark-based cannulation to insert venous access via the subclavian vein in adults.

American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists in 2011 came up with guidelines[37] for performing ultrasound guided vascular cannulation.In jugular vein cannulations they recommended that properly trained clinicians should use real-time ultrasound during IJV cannulation whenever possible to improve cannulation success and reduce the incidence of complications associated with the insertion of large-bore catheters. Their opinion on USG guidance in subclavian vein cannulation was less supportive. They felt that high-risk patients may benefit from ultrasound screening of the subclavian vein before attempted cannulation to identify vessel location and patency and to specifically identify thrombus before attempted cannulation.

Buzançais et al[38] compared infraclavicular axillary vein and infraclavicular subclavian veincannulation with ultrasound in a randomized controlled non inferiority trial. First attempt success rates were 87.7% for subclavian vein and 85.5% for axillary vein. The overall success rates was 96.5% for subclavian group and 98.4% for axillary vein groups. He concluded that in terms of absolute success rate, the axillaryvein approach is not inferior to subclavian vein approach. However, he reported higher complications with axillary vein group when compared subclavian. He reported four arterial punctures (6.5%) in axillary vein group when compared to two arterial punctures (3.3%) in subclavian vein group. He also reported seven instances of catheter malposition (11.3%) in axillary vein cannulation when compared to two cases of malposition in subclavian vein group (3.3%). The higher incidence of complications in the study with axillary vein approach prompted the author to suggest it to be considered as a rescue alternative, after failure of subclavian vein approach.

Ultrasound imaging can be used for pre-locating the vein and marking the site before puncture or it can be used for continuously visualizing the needle and the vein during the catheterization procedure (Real time guidance). When using real time guidance the vein can be visualized either in short axis (as a circular structure) or in long axis. Both these methods have been used in literature and compared. ***Vogel et al***[39] compared long axis and short axis views for internal jugular and subclavian vein cannulations in mannequins and found that posterior wall punctures were lesser with long axis views. They postulated that the lesser number of posterior wall punctures will translate into lesser complications in central venous catheterizations.

Moore et al[40] in his article described the importance of ultrasound in the present era, not just for central venous access but also for central or peripheral arterial access and peripheral venous access. He concluded that USG guidance can increase success anddecrease complications in a wide variety of vascular access procedures. He also suggests the use of USG as a first line standard for central venous and arterial access. He also emphasizes on the importance of training the physicians involved in these procedures on the use of ultrasound.

ALTERNATE ROUTES OF CENTRAL VENOUS ACCESS

Central venous catheterization becomes a mandatory part of anesthesia in most of the cardiac and vascular surgery patients for both monitoring as well as for administration of vasoactive drugs. The ideal venous access site for cardiovascular surgery is not clearly defined. Femoral vein is not commonly used because of the higher incidence of mechanical complications, inability to access the site during surgery, inability to measure the SVC saturations and higher incidence of infectious complications. Infraclavicular subclavian has some disadvantages like higher rate of serious mechanical complications, a higher incidence of catheter malposition and pertaining to cardiac surgery there is a risk of catheter getting kinked after the application of sternal retractor.

Internal jugular route although popular, has its own disadvantages like higher incidence of accidental arterial puncture and higher rate of catheter related infections. There are also reports of fatalities due to stroke following accidental carotid arterial puncture on attempted IJV cannulation.

Reuber et al in his paper reviewing stroke after jugular vein catheterization reported four instances of stroke following carotid puncture on attempted jugular vein cannulation. Two of them presented after 24 hours among which one patient expired.

They warned the clinicians to be wary of this complication especially in those with atherosclerotic disease of the carotid artery. The patient population presenting for coronary bypass surgeries have higher risk of developing atherosclerotic disease in other vascular beds like carotid, making them prone for such a complication. Similar case reports have been published in literature by ***Sloan et al***[41]where accidental puncture of vertebral artery during attempted jugular vein catheterization resulted in massive brainstem stroke and death.

Subclavian vein cannulation through an infraclavicular approach has also been used in patients undergoing cardiac surgeries. The higher incidence of pneumothorax in case of subclavian vein catheterization was one of the major concerns with the selection of this route. In addition, with respect to cardiac surgery the subclavian venous catheter can get kinked after sternotomy and sternal retraction.

Mantia et al[42] reported a 45% incidence of pulmonary artery catheter malfunction when subclavian route was used, where they experienced a loss of pulmonary artery catheter trace after sternal retraction. Many centers now prefer to catheterize internal jugular vein for cardiothoracic surgeries.

Other routes like supraclavicular subclavian or innominate, and the axillary vein approaches are less explored for central venous access in cardiac surgeries. These routes have consistently demonstrated its high success rates, similar or less complication rates including infections in various studies in literature.

In one of the early studies ***Brahos et al***[43] described the technique of supraclavicular subclavian vein access in 250 cases and found it a viable route for central venous access.

There is a renewed interest in this technique in the last 2 decades with various studies demonstrating its safety and ease of access. It has some specific advantages over infraclavicular subclavian access like easier access, easily identifiable landmarks and the possibility of access while continuing resuscitative efforts.

Patrick et al[44] reviewed the studies on supraclavicular subclavian vein catheterizationusing various techniques and found a success rate ranging from 95-100%. The use of ultrasound in this approach was also reviewed and the primary hindrance for its use was found to be the lack of space for the probe in the area.

Pirotte et al[45] demonstrated the use of USG for subclavian vein cannulation in children. In his study he used the ultrasound to demonstrate the course of the subclavian vein and to mark the puncture point of the needle. He thus used a supraclavicular visualization of the vein to make an infraclavicular puncture and subsequent cannulation. He reported a 100% success rates for the technique with 84% first attempt success rates.

Breschnan et al[46] have described the use of ultrasound for supraclavicular brachiocephalic vein cannulation in 35 pediatric patients. He reported a 100% success rate with the technique with 73.8% first attempt success rates. He reported that higher number of needle passes and puncture attempts were needed in smaller patients.

Rhondali et al[47]studied supraclavicular subclavian vein cannulation with an in plane approach. In his observational study he studied 37 catheterizations in children and reported a 100% success rate and 81% first attempt success rates. He reported one pneumothorax and one arterial puncture and these were attributed to the inexperience of the operator.

Infraclavicular axillary vein catheterization was introduced as an alternative to subclavian vein catheterization with lower incidence of pneumothorax and similar success rates. The landmarks for axillary vein catheterization was described by ***Nickalls et al***[17]**.** In the era of ultrasound, its usefulness in axillary vein catheterization has also been demonstrated. ***O'Leary et al***[48] in a retrospective study reported 99.5% success in ultrasound guided axillary vein catheterization. Infraclavicular axillary vein cannulations have not been studied in adult cardiac surgical patients.

AIMS AND OBJECTIVES

AIMS AND OBJECTIVES

PRIMARY OBJECTIVE

To evaluate the success rates of central vein catheterization by four various routes, i.e internal jugular, supraclavicular subclavian, infraclavicular subclavian and infraclavicular axillary vein under real time ultrasound guidance in patients undergoing cardiovascular surgeries.

SECONDARY OBJECTIVES

To compare the following in the four groups.

1. First attempt success rates
2. Time taken for venous access and catheterization
3. Catheter malfunction
4. Catheter malposition
5. Complication rates

MATERIALS AND METHODS

MATERIALS AND METHODS

Study design:

A prospective, randomized study was conducted in the Department of Cardiovascular & Thoracic Anesthesiology in SCTIMST, Thiruvananthapuram. After Institutional ethics committee approval and written informed consent, two hundred patients were included in the study. The patients were randomly assigned to four groups, each having equal number of patients. Randomization was done by a closed-envelope method.

Selection of Patients:

Two hundred patients of age 18 to 80 years, scheduled for elective cardiovascular surgery who required central venous catheterization, were taken up for the study. The patients were randomly allocated to one of the four groups (50 in each group).

All the patients had their central venous catheter inserted under real time ultrasound guidance. Patients of first group had their catheter inserted in the subclavian vein through the supraclavicular approach (SSV group). Patients in second group, the catheterization was done in the internal jugular vein (IJV group). In patients of the third group, axillary vein was catheterized through an infraclavicular approach (IAX group) and in the last group the subclavian vein was catheterized under real time ultrasound guidance in the infraclavicular area (ISV group)

Inclusion Criteria

- Age between 18 and 80 years
- American Society of Anesthesiology (ASA) class below 4

Exclusion Criteria

- Coagulopathies/ patient on heparin or warfarin
- Distorted chest anatomy
- Superior Vena Cava Syndrome
- Infection at the cannulation site
- Pregnant patients
- BMI > 30

PREPARATION AND TECNIQUE

All patients were monitored with ECG, blood pressure and pulse oximeter and the catheterization was done after the induction of anesthesia in the operating room (OR). All patients were placed in supine position with 20-30° Trendelenburg tilt to distend the veins and to minimize accidental air embolism. The appropriate area was prepared with antiseptic solution (10% Povidone-Iodine solution) and sterile drapes were used to provide maximum barrier precautions during the procedure. After proper positioning, cleaning and draping as described above, a 7.5 MHz transducer of the ultrasound device (eSoate US system) was used to obtain a 2D image display. Transducer wrapped in sterile sheath with ultrasonic gel, was placed at the appropriate level to visualize the vein. Compressibility of the vein and visible pulsations of the artery were observed in all patients. The Doppler profile across the vessel showing a continuous flow pattern and the use of bubble contrast in the ipsilateral arm were utilized to differentiate vein from artery whenever required.

Figure 1 – esaoteMy lab one USG machine

Technique of Internal jugular vein catheterization

After positioning and preparation as described, transducer wrapped in sterile cover was kept on the neck at the level of cricoid cartilage perpendicular to skin to obtain the image of carotid artery and internal jugular vein in short axis on the screen, with jugular vein in the center. After identifying the vein from artery by the compressibility, loss of pulsatility and Doppler profile showing continuous flow, puncture was made and the needle tip was directed into the vein under vision. Successful puncture was identified by the free flow of dark red blood in the syringe. Guide wire was inserted through the needle and the position of the guide wire was demonstrated in the jugular vein. Catheterization was completed by threading the triple lumen catheter over the guide wire. Proper functioning of all three ports were confirmed by aspirating blood from all ports.

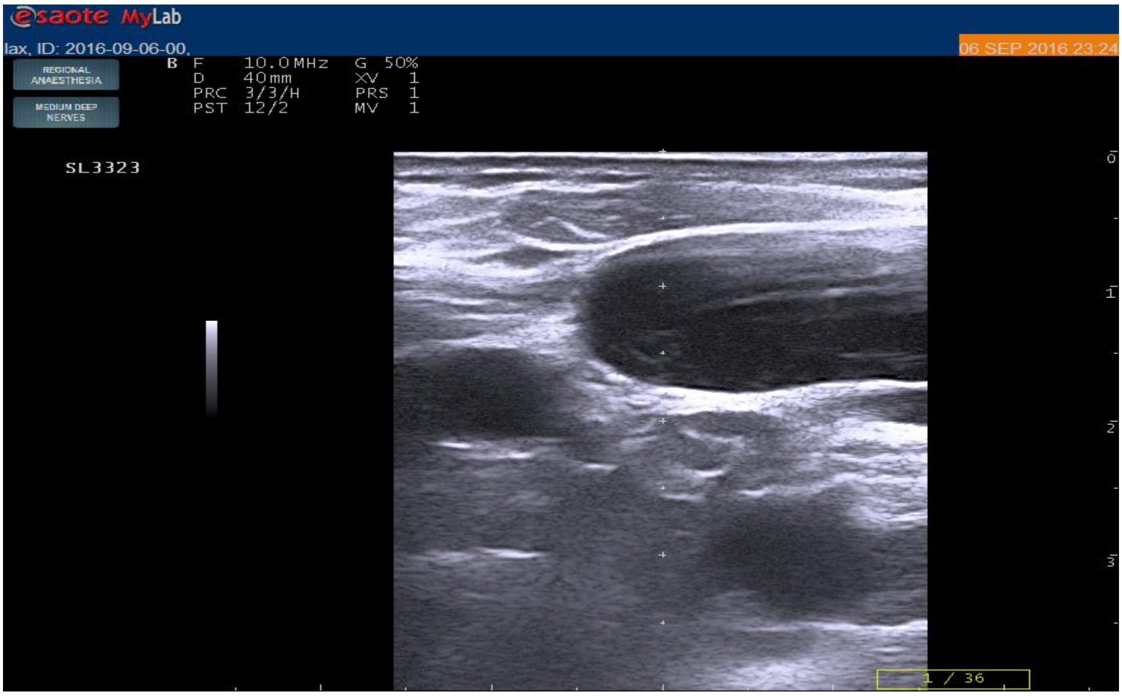


Figure 2. Internal Jugular vein in Short axis

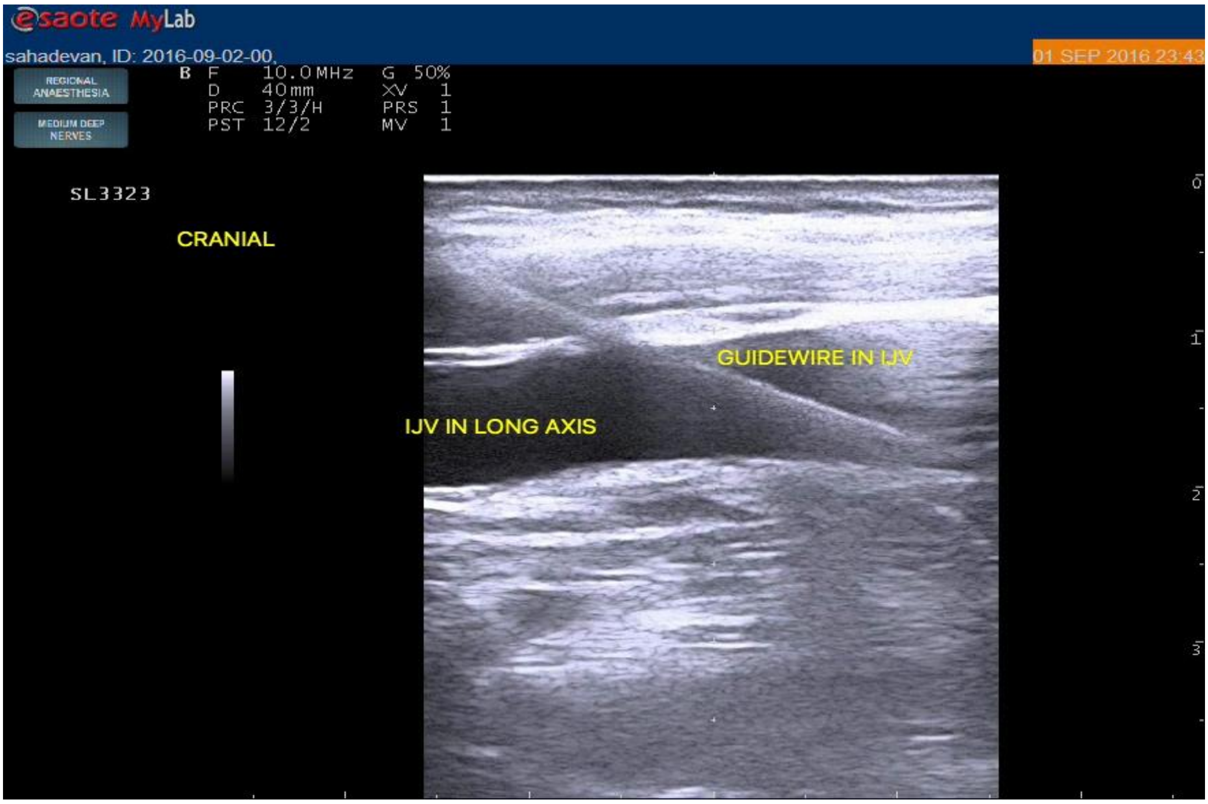


Figure 3. Demonstrating guidewire in IJV

Technique of infraclavicular axillary vein catheterization.

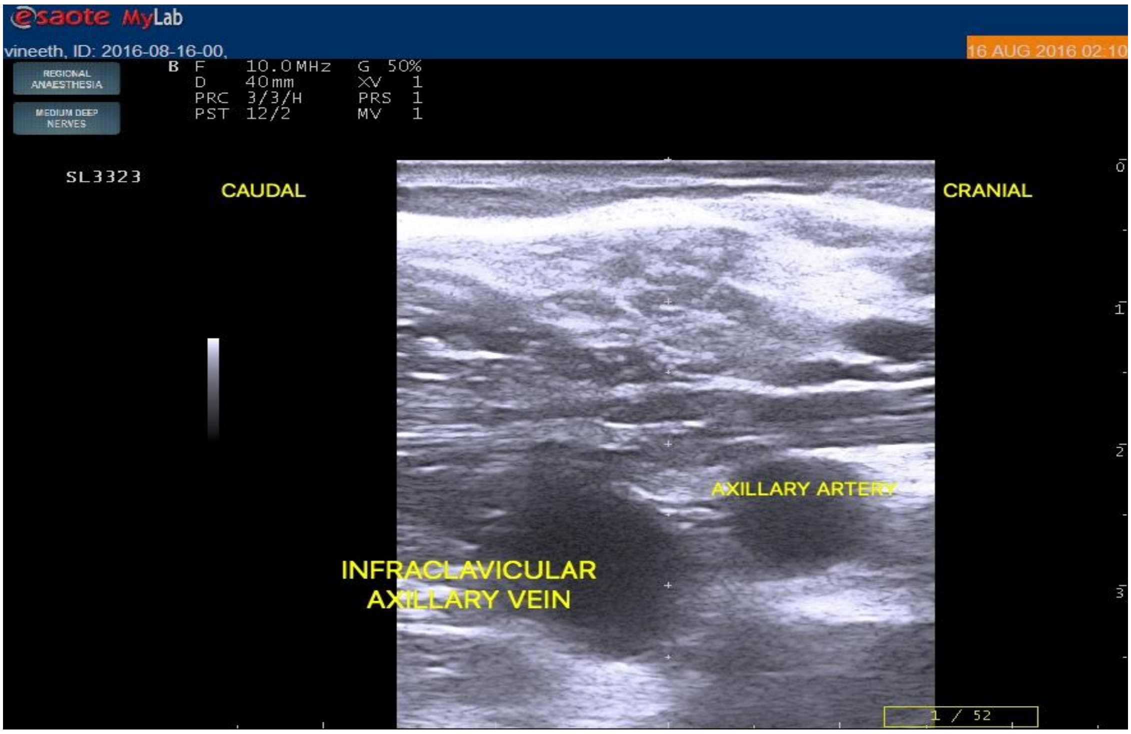


Figure 4. Infraclavicular axillary vein in short axis

Patient was kept in 20-30 degrees Trendelenburg position with arms by the side and head in neutral position. Sterile preparations were taken as mentioned earlier. Ultrasound probe covered in a sterile cover was kept on the chest wall in the infraclavicular area to get axillary vessels in short axis as shown in the picture. Mechanical ventilation was discontinued and the patient was disconnected from ventilator. All efforts were taken to keep the needle tip under vision when needle was being introduced. Puncture of the vein was identified by free aspiration of dark blood in the syringe. After guide-wire insertion, the ultrasound was used to demonstrate the guide-wire traversing the subclavian vein and entering the brachiocephalic vein by keeping the probe in the supraclavicular area. Catheterization was completed using Seldinger technique.

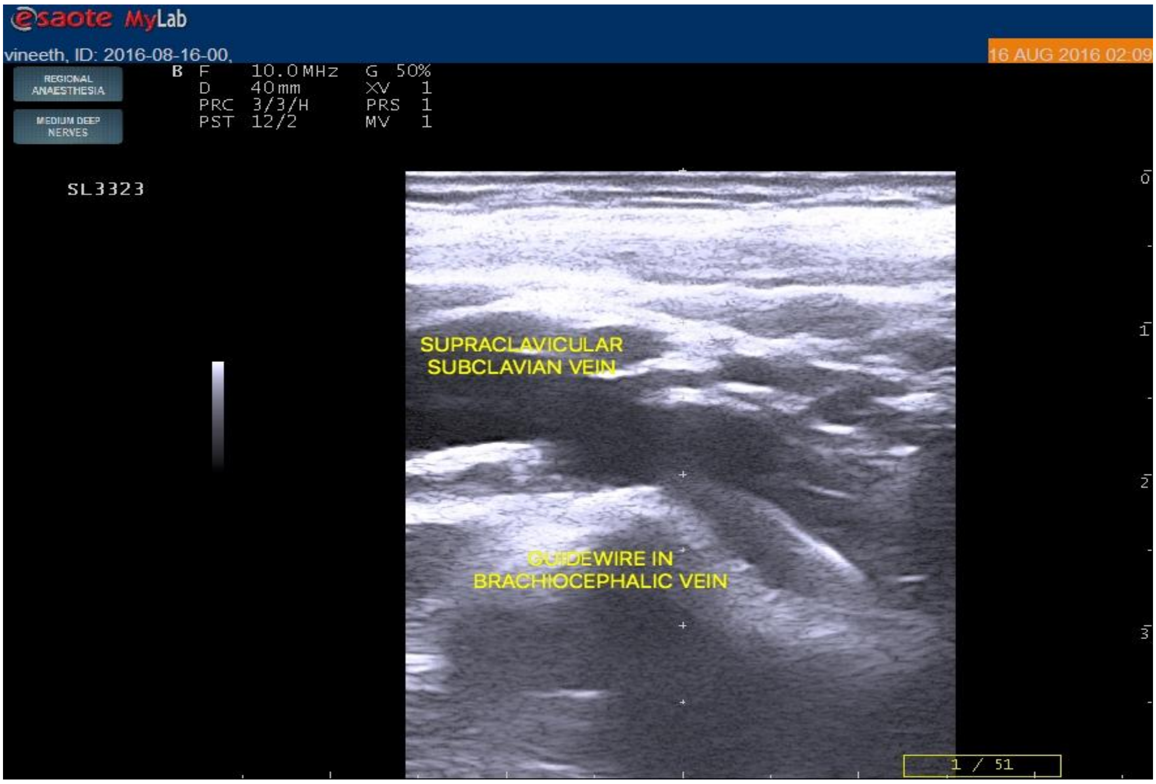


Figure 5. Demonstrating guidewire in brachiocephalic vein from supraclavicular view

Technique of Infraclavicular subclavian vein catheterization

Patient was kept in 20-30 degree Trendelenburg position with arms by the side and head in neutral position. Sterile preparations were taken as mentioned earlier. Ultrasound probe covered in a sterile cover was kept on the chest wall below the clavicle as shown in the picture to get clavicle cranially and subclavian vessels in short axis view caudally (Figure: 6). Mechanical ventilation was discontinued and the patient was disconnected from ventilator. The needle was introduced under real time ultrasound guidance and the needle tip was visualized till it enters the vein and a free aspirate of blood was obtained in the syringe. Using supraclavicular view, guide-wire was demonstrated in the subclavian vein entering the brachiocephalic vein (Figure: 7). Catheterization was completed using Seldinger method.

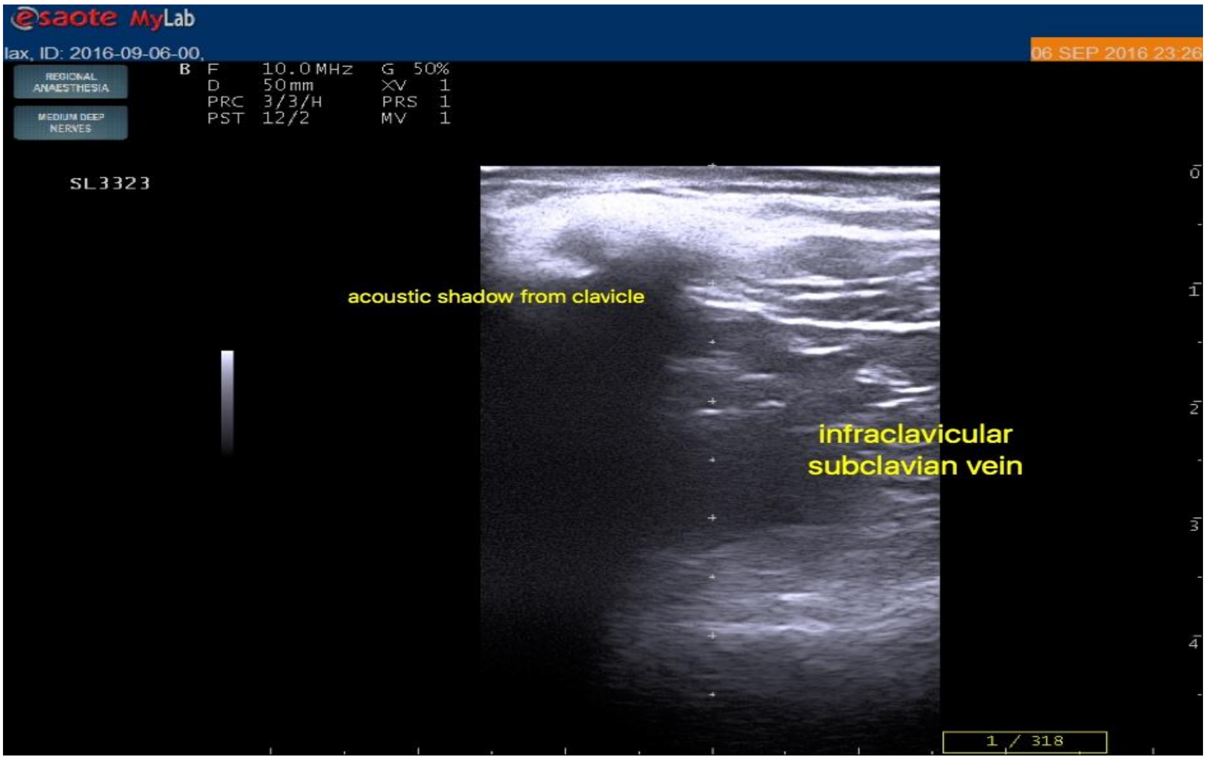


Figure 6. Infraclavicular subclavian vein in short axis

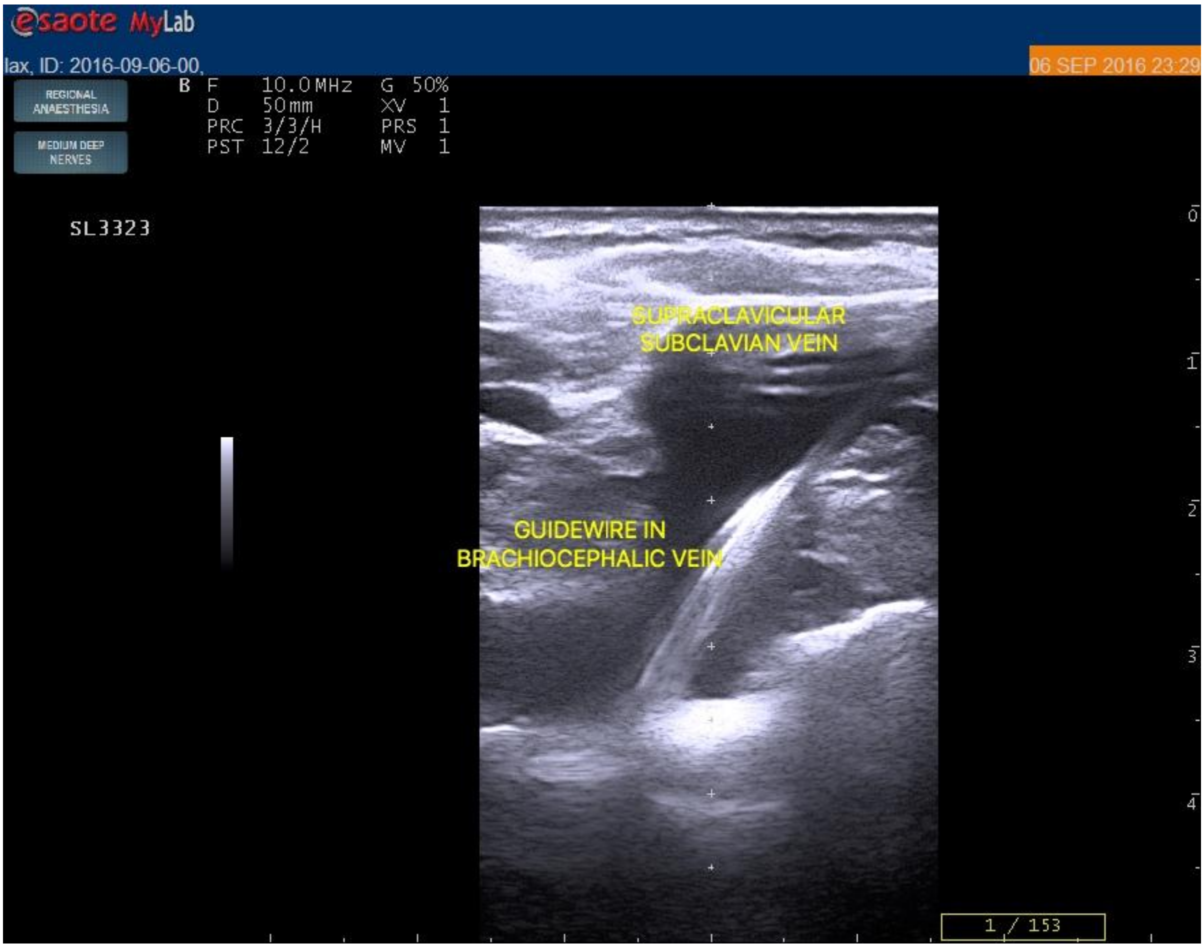


Figure 7. Demonstrating guidewire in brachiocephalic vein from supraclavicular view

Technique of supraclavicular subclavian vein catheterization

Patient was kept in 20-30degree Trendelenburg position with head slightly rotated to contralateral side. After proper sterile preparations, USG probe was kept in the supraclavicular area to obtain the supraclavicular subclavian vein in long axis (Figure: 8). Mechanical ventilation is discontinued and the patient is disconnected from ventilator. The needle was introduced under real time ultrasound guidance and the needle tip was visualized till it enters the vein and a free aspirate of blood is obtained in the syringe. In the same view, guide-wire was demonstrated in the subclavian vein entering the brachiocephalic vein. Catheterization was completed using Seldinger method.

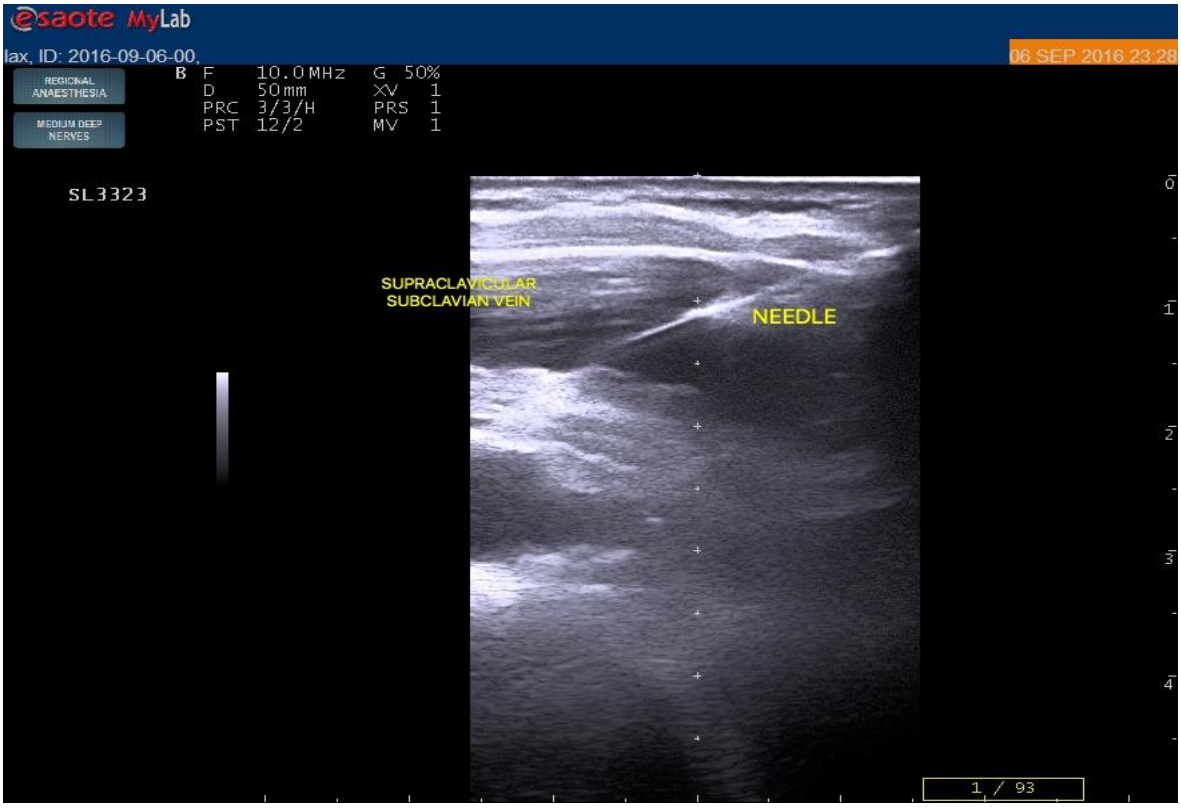


Figure 8. Supraclavicular subclavian vein being cannulate

OBSERVATIONS

Demographic data

- Age
- Sex
- Weight
- Body Mass Index (BMI)

During catheterization by all four methods following observation was recorded by an independent observer:

- Number of attempts
- Success rate
- Venous access time*
- Catheterization time*
- Catheter malfunction during surgery*.
- Malposition*
- Complications
    - Hematoma
    - Subclavian/ Carotid artery puncture
    - Pneumothorax
    - Hemothorax

More than three attempts will be taken as a *failure.*

**Venous access time*is defined as the time from the beginning of scanning until free aspiration of blood.

**Catheterization time*is defined as the time from the starting of insertion of the introducer needle to the end of catheter placement not including the suturing and fixation time.

**Catheter malfunction* is defined as any loss of CVP trace on the monitor or inability to aspirate blood freely from any of the three ports of the triple lumen catheter during surgery.

**Catheter malposition* defined as position of the tip of the catheter anywhere within 2 cms from the SVC - RA junction or in the upper RA.

In case of any accidental arterial puncture or pneumothorax, further attempts by the same approach were not undertaken and catheterization was done using an alternate route.

Complications, if occurred,were managed according to the standard protocol.

OBSERVATIONS AND RESULTS

OBSERVATIONS AND RESULTS

Two hundred patients were enrolled in this randomized study. Patients were randomly allocated into four groups, 50 in each group. In the first group of patients central venous catheterization was done via Internal jugular vein (IJV Group); in the second group, catheterization was done via infraclavicular axillary vein (IAX Group); in the third group, infraclavicular subclavian vein (ISV Group) was catheterized and in the last group catheterization was done via supraclavicular subclavian vein (SSV Group). Central venous catheterization was not possible in seven patients through the approach they were designated to, hence catheterization was performed via IJV which was selected as the first rescue approach.

Statistical analysis was performed using GraphpadInstat software.

Demographic data (age, weight, height, body mass index) were compared using one way Analysis Of Variance (ANOVA) and sex distribution was compared by using chi-square test.

Non-parametric data (venous access time and catheterization time) were compared using the Kruskal-Wallis test and subgroup analysis was done using Dunn's multiple comparisons test.

Success rates, first attempt success rates, complications (arterial puncture, pneumothorax, malposition, malfunctions) were compared by applying the Chi-square test and the Fisher's exact test.

A 'p' value of <0.05 was taken to be statistically significant for all parametric and categorical data in this study. The following observations were made

DEMOGRAPHIC DATA

The demographic parameters were compared among the four groups and there were no statistical difference between the four groups with respect to age, weight, sex distribution and BMI.

Table 1.Demographic Data

	IJV Group	IAX Group	ISV Group	SSV Group	'p' Value
AGE (years)	**51.46 (± 15.36)**	**54.98 (±15.36)**	**53.26 (± 13.79)**	**53.8 (±14.16)**	**0.624**
WEIGHT (kgs)	**66.36 (± 8.85)**	**68.4 (±9.16)**	**65.24 (± 9.25)**	**64.66 (± 9.14)**	**0.137**
BMI (kg/m^2)	**23.32 (±1.009)**	**23.76 (± 0.978)**	**23.17 (± 1.71)**	**23.35 (± 1.635)**	**0.1743**

All values expressed as mean±standard deviation (SD)

The majority of the patients included in the study were males (73.5%) and only 53 patients

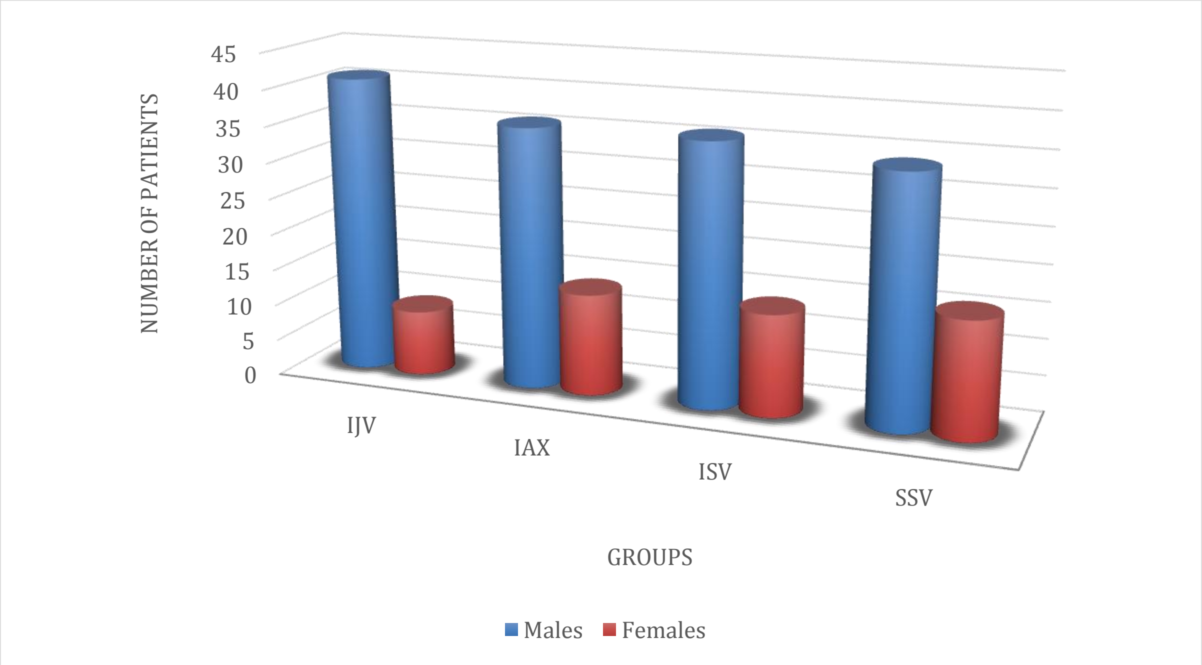
(26.5%) were females. However, the male – female distribution was similar among the four groups ('p' value 0.432)

Table 2. Sex distribution of patients in four groups

	Total (n = 200)	IJV group (n = 50)	IAX group (n = 50)	ISV group (n = 50)	SSV group (n = 50)	P value
Male; n (%)	**147 (73.5%)**	**41**	**36**	**36**	**34**	**0.432**
Female; n (%)	**53 (26.5%)**	**9**	**14**	**14**	**16**	

n = number

Fig: 9 SEX DISTRIBUTION



SUCCESS RATES

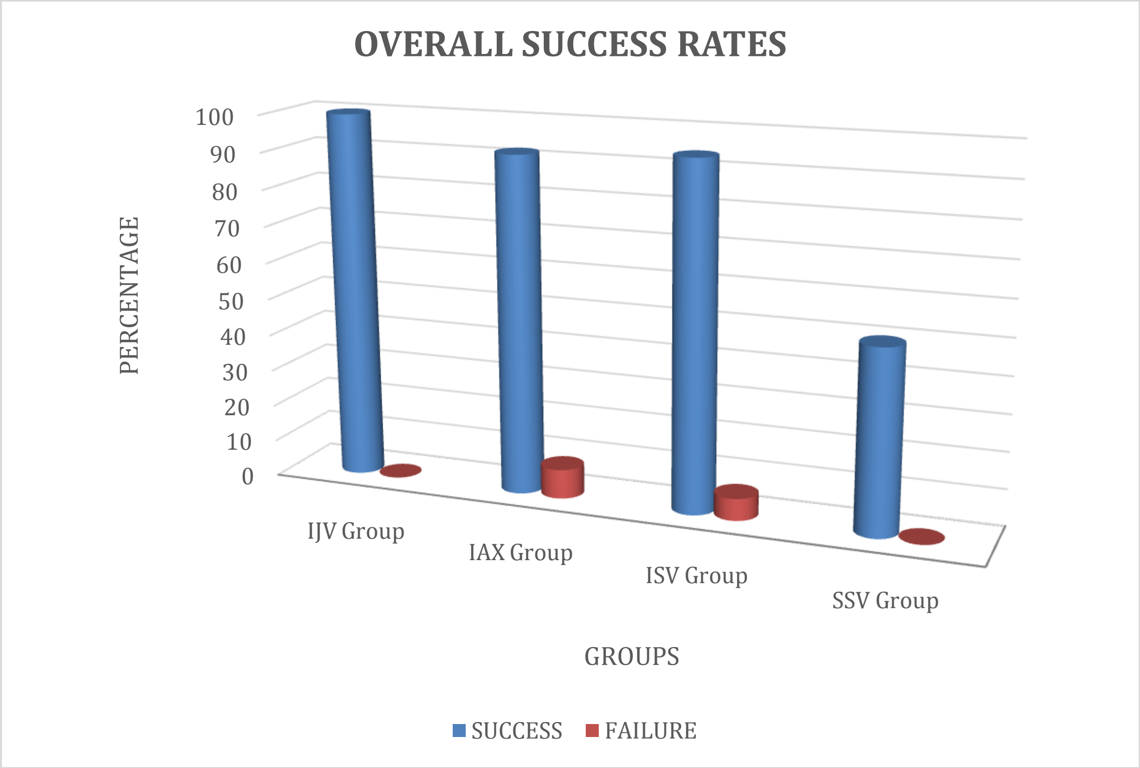
Successful catheterization (defined as success with ≤ 3 attempts) could be achieved in 193 (96.5%) patients. All the patients in IJV and SSV group were catheterized within three attempts. In 4 patients (8%) in IAX group and 3 patients (6%) in the ISV group catheterization through the designated approach was unsuccessful. However, on comparison, the differences in the overall success rates were not statistically significant (‘*p’ value*- 0.86) among four groups.

Table 3. Overall success rate

Group	**IJV group**	**IAX group**	**ISV group**	**SSV group**	**‘p’ Value**
Success; n (%)	**50 (100%)**	**46 (92%)**	**47 (94%)**	**50 (100%)**	**0.86**
Failure; n (%)	**0**	**4 (8%)**	**3 (6%)**	**0**	

Fisher’s exact test, n = number

Fig:10 Overall success Rates



FIRST ATTEMPT SUCCESS RATES

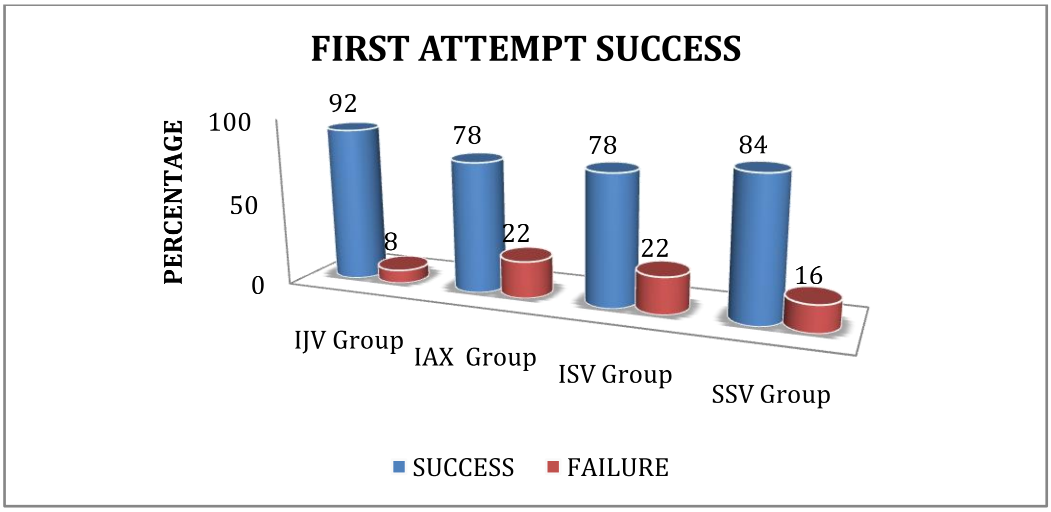
First attempt success rates were achieved in 92% (46 patients) of the IJV group, 84% (42 patients) of the SSV group, 78% (39 patients) of the IAX group, and 78% (39 patients) of the ISV group. On statistical analysis the difference in the first attempt success rates between the four groups were not statistically significant ('p' value - 0.1970)

Table4. Successful Cannulation in first attempt

First Attempt Success	**IJV group**	**IAX group**	**ISV group**	**SSV group**	**'p' value**
Success n (%)	**46 (92%)**	**39 (78%)**	**39 (78%)**	**42 (84%)**	**0.1970**
Failure n (%)	**4 (8%)**	**11 (22%)**	**11 (22%)**	**8 (16%)**	

Fisher's exact test, n = number

Fig:11 First attempt Success Rates



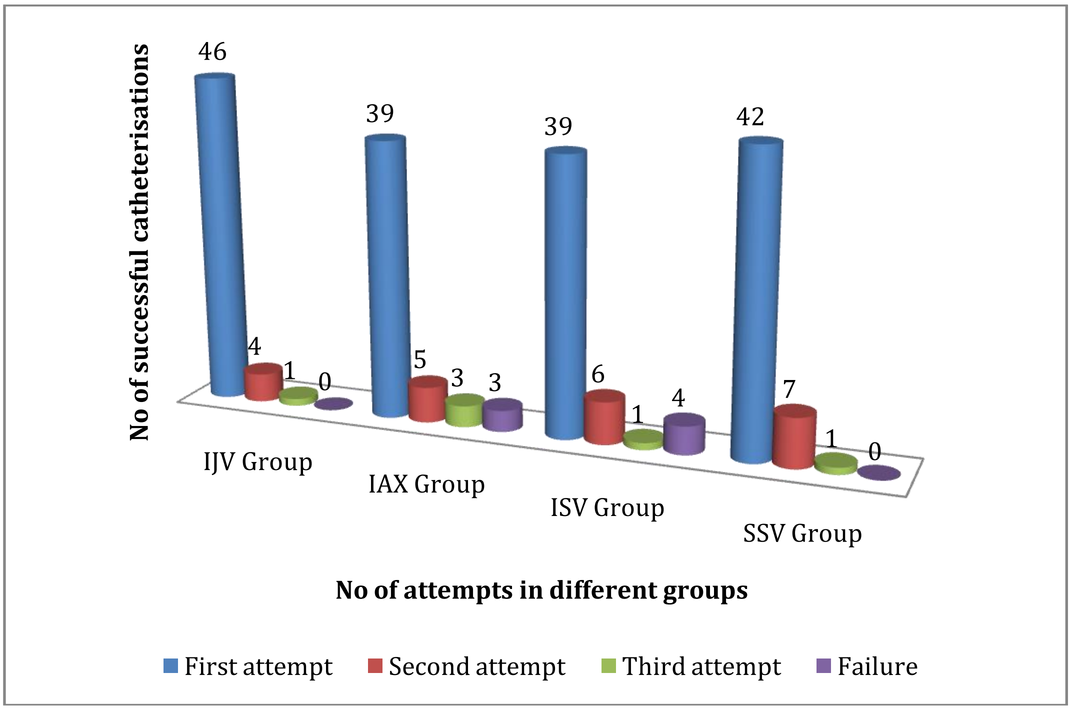
CATHETERIZATION WITH MULTIPLE ATTEMPTS

Table 5. Successful catheterization with increasing number of attempts

SUCCESS RATES	IJV	IAX	ISV	SSV
FIRST ATTEMPT N (%)	**46 (92%)**	**39 (78%)**	**39 (78%)**	**42 (84%)**
SECOND ATTEMPT N (%)	**4 (8%)**	**5 (10%)**	**6 (12%)**	**7 (14%)**
THIRD ATTEMPT N (%)	**0**	**3 (6%)**	**1 (2%)**	**1 (2%)**
FAILURE	**0**	**3 (6%)**	**4 (8%)**	**0**

The success rates with increasing number of attempts is shown in the table given above. Second attempt was successful in 8% of patients in IJV group, 10% of patients in the IAX group, 12 % of patients in the ISV group and in 14% of patients in the SSV group. A third attempt was successful in 6% of patients in IAX group, 2% of patients in ISV group and 2% of patients in SSV group. Catheterization by the designated approach failed in 7 patients and was achieved through Internal jugular approach. 6% of patients in IAX group and 8% of patients in the ISV group could not be catheterized.

Fig:12Successful catheterization with increasing number of attempts



VENOUS ACCESS TIME

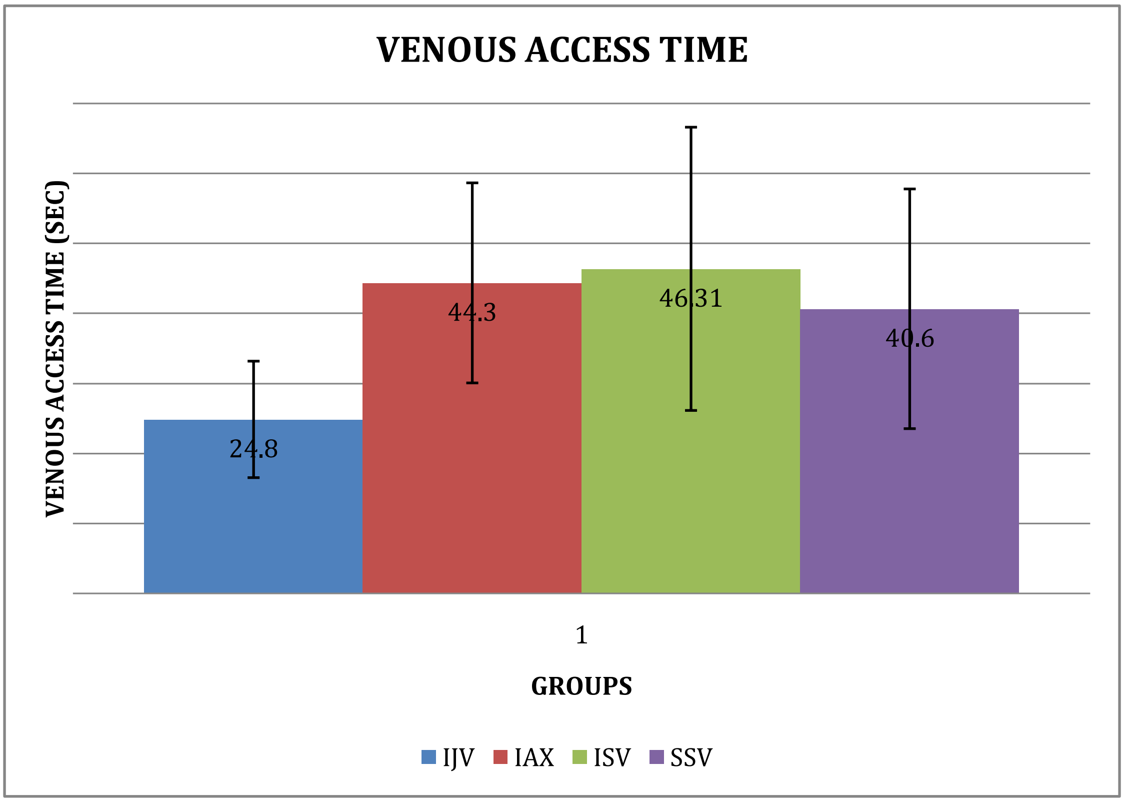
Table 6. Venous Access Times

Groups	IJV GROUP	IAX GROUP	ISV GROUP	SSV GROUP	'p' VALUE
Median venous access time sec. (min-max)	**22 (14 – 55)**	**38.5 (24 – 84)**	**40 (22 – 113)**	**37 (20 – 136)**	**<0.001**

Mean venous access time (defined as the time from the beginning of scanning tofree aspiration of blood) was found to be 24.8 sec in IJV group, 44.3secin IAX group,46.1sec in ISV group and 40.6sec in the SSV group. The median venous access time was 22 sec., 38.5 sec, 40 sec and 37 sec. in IJV, IAX, ISV and SSV groups, respectively. The venous access times were compared among the four groups using *Kruskal-Wallis* test and statistical difference was found between the groups with respect to cannulation times(P < 0.001).

On post hoc analysis using *Dunn's multiple comparison* test, the difference in venous access times between the IJV group and each of the other three groups were found to be statistically significant. The venous access time of IAX group was found to be statistically not different from that of ISV group and SSV group. The venous access time of ISV group was also found to be not statistically different from that of SSV group.

Fig: 13 Venous Access Times



CATHETERIZATION TIMES

Table 7. Catheterization Times

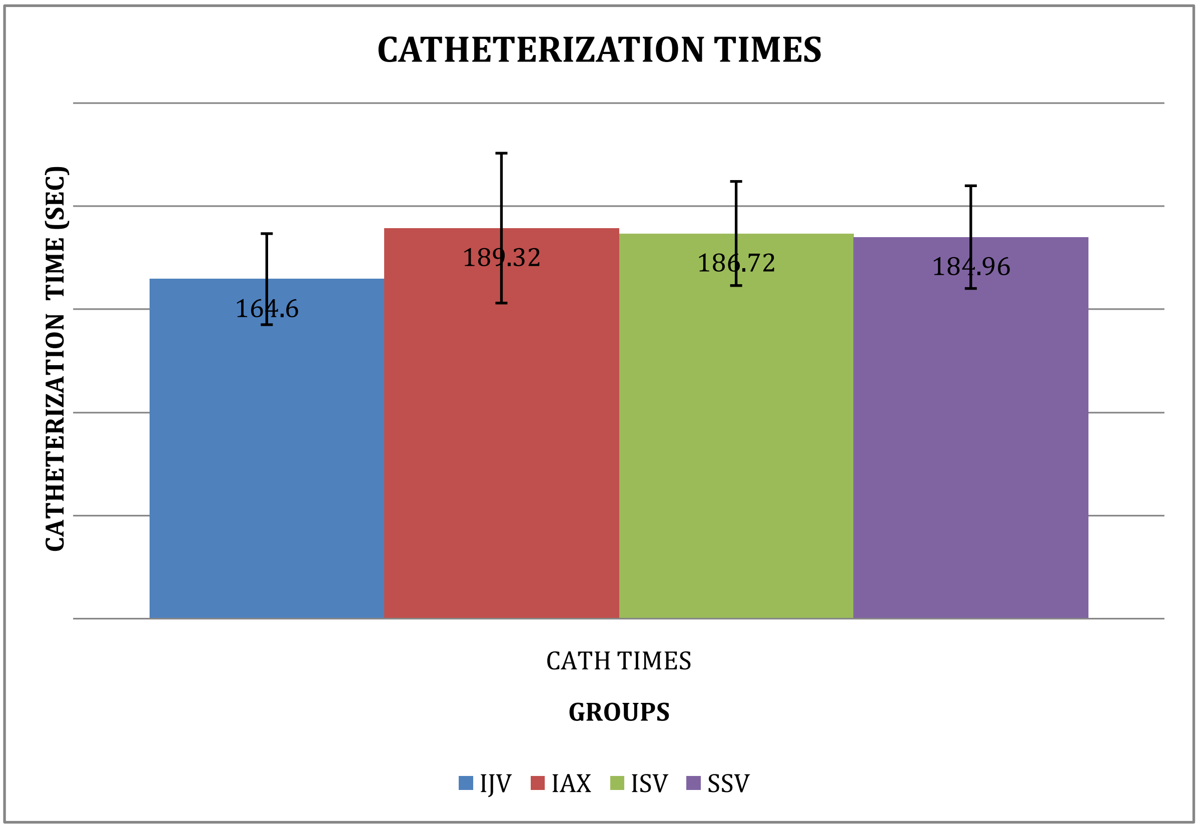
Groups	**IJV GROUP**	**IAX GROUP**	**ISV GROUP**	**SSV GROUP**	**'p' VALUE**
Median catheterization time sec. (min-max)	**157 (132-218)**	**183 (132-339)**	**180 (139- 265)**	**184.5 (139 – 265)**	**<0.001**

Kruskall-wallis test
Multiple comparisons between groups by Dunn multiple comparison test.

Mean catheterization time was found to be 164.6 sec in IJV group, 189.3 seconds in IAX group, 186.72 seconds in ISV group and 184.96 seconds in SSV group. The median catheterization time was 157 sec.,183 sec, 180 sec and 184.5 sec. in IJV, IAX, ISV and SSV groups respectively. The catheterization times were compared among the four groups using *Kruskal-Wallis* test and statistical difference was found between the groups with respect to cannulation times(P < 0.001).

On post hoc analysis using *Dunn's multiple comparison*test, the difference in catheterization times between the IJV group and each of the other three groups were found to be statistically significant. The catheterization times of IAX group was found to be statistically not different from that of ISV group and SSV group. The catheterization time of ISV group was also found to be not statistically different from that of SSV group.

Fig :14 Catheterization Times



CATHETER MALFUNCTION

There were no instances of catheter malfunction in the IJV and the SSV groups. 4 patients (8%) of IAX group and 7 patients (14%) in ISV group had catheter malfunction. On analysis using chi square test the difference in incidence of catheter malfunction was statistically significant (P value 0.0026) when all the four groups were compared.

On intergroup comparison using *Fischers exact test*, the difference in the incidence of catheter malfunction was statistically significant between the IJV group and both IAX and ISV groups . Similarly, there was a statistically significant difference in catheter malfunction incidence between theSSV group and IAX and ISV groups.

Table 8. Incidence of catheter malfunctions

Catheter Malfunction	**IJV Group**	**IAX Group**	**ISV Group**	**SSV Group**	**P Value**
Yes n (%)	**0 (0 %)**	**4 (8.7%)**	**7 (14.9%)**	**0 (0%)**	**0.0026***
No n (%)	**50 (100%)**	**42 (91.3%)**	**40 (85.1%)**	**50 (100%)**	

Chi square test, n = number

Table 9. Catheter malfunction between groups -1

Catheter Malfunction	IJV/SSV group*	IAX Group	p value
Yes n (%)	**0**	**4 (8.7%)**	**0.0491***
No n (%)	**50 (100%)**	**42 (91.3%)**	

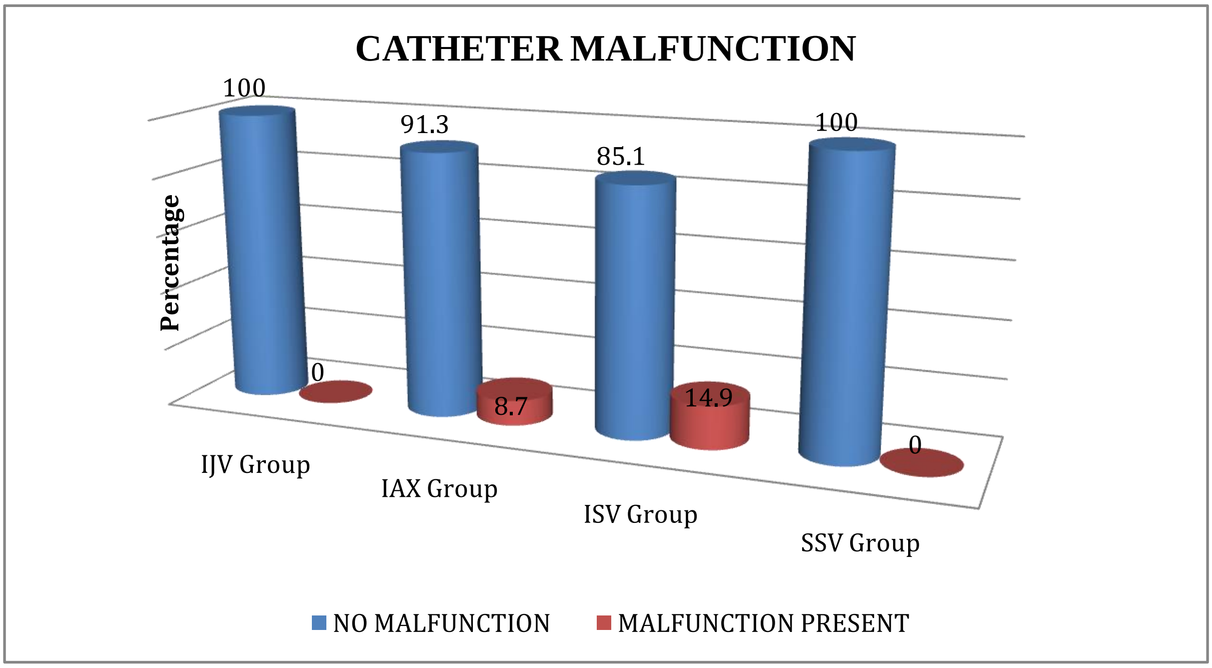
Fischers exact test
** Both had same number of catheter malfunction*

Table 9. Catheter malfunction between groups -2

Catheter Malfunction	IJV/SSV group	ISV Group	p value
Yes n (%)	**0**	**7 (14.9%)**	**0.0049***
No n (%)	**50 (100%)**	**40 (85.1%)**	

- *Fischers exact test*

Fig: 15 Catheter Malfunction



CATHETER MALPOSITION

There were only two instances of catheter malposition in our study, one in the jugular group where the catheter went into ipsilateral subclavian vein and one in the subclavian vein where it went into the ipsilateral jugular vein.

COMPLICATIONS

Inadvertent arterial puncture occurred in two patients, one in IAX group and one in the ISV group. There was a single episode of pneumothorax in the ISV group. None of the patients in SSV group or the IJV group had any serious mechanical complications.

DISCUSSION

DISCUSSION

The intention of our study was to evaluate the best route of central venous access in patients undergoing cardiovascular surgery. We evaluated the success rates, first attempt success rates, venous access and catheterization times, malfunctions and complications in four approaches to central venous access. Ultrasound guidance has consistently shown to improve success rates and /or minimize complications in central venous access by various routes. Various international guidelines also advocate the use of USG guidance for these procedures.We, therefore decided to include USG guidance as a part of the study protocol.

SUCCESS RATES

Success rate of catheterization was 100% for the IJV and supraclavicular subclavian (SSV) groups, 92% in the infraclavicular axillary (IAX) group and 94% in the infraclavicular subclavian (ISV). These success rates are similar to those of published studies[28, 38,46, 49].

The high success rate in the IJV and SSV groups are attributed to two reasons, one is the experience of the operators in USG guided cannulation by these routes and the other is the ease of imaging of these vessels due to their superficial locations. The relatively superficial position of these vessels makes it easier to visualize and cannulate using USG. The infraclavicular subclavian or axillary vein is difficult to visualize with USG when compared to IJV or the supraclavicular subclavian vein. ***Stachura et al***[50] compared the visualization of subclavian in supraclavicular and infraclavicular views and reported an excellent view in 66.3 to 71.5% of patients in supraclavicular views and in only 37.8 to 38.8% of patients in infraclavicular views.

A similar difficulty in visualizing the deeper infraclavicular subclavian and axillary veins directly translated into lower success rates and longer access times in our study.

The overall success rate of infraclavicular axillary vein in our study was 92 % and first attempt success rate of 78% which is similar to reported rates of ultrasound guided axillary vein cannulation in literature**.**

Czarnick et al[51] in his study of USG guided axillary vein cannulation for renal replacement therapy reported 93% success rates, with a first attempt success rate of 75.9%. His reported mechanical complications were also similar to that of the IAX group in our study.In his study they used long axis view of the vein for cannulation whereas we used short axis view in IJV, infraclavicular subclavian and axillary vein cannulations.

We limited our number of attempts to three or till a serious mechanical complication had happened. The incidence of serious complications has been shown to increase with repeated attempts and this prompted us to avoid further attempts at the same site after three failed attempts or an inadvertent arterial puncture or pneumothorax.

First attempt success rates were higher in the IJV group when compared to other groups, although the difference was not statistically significant. The familiarity of the investigators to the IJV cannulation also may have added to the higher success rates observed in our study. The first attempt success rates in axillary and infraclavicular subclavian veins were slightly lower at 78%. The first attempt success rates in ultrasound guided infraclavicular subclavian vein access in literature is between 66 to

75% irrespective of whether USG guidance was used or not[52].This shows the non-superiority of USG guidance in improving the first attempt and overall success rates.

Brass et al[36] in a meta analysis on the use of USG in infraclavicular subclavian approach found no conclusive evidence for a reduction in complications, number of attempts until success or first-time success rates or time taken to insert the catheter. Our overall success rates of 94% and a first attempt success rate of 78% is similar to success rates reported in landmark technique[24,53].

We chose the short axis view for cannulations since most of the anesthesiologists involved in the study were more experienced with the use of this view for guiding cannulations. Literature shows a higher first pass success rates and fewer needle redirections when short axis views were used.

VENOUS ACCESS TIMES

Mean venous access time in our study was found to be 24.8 seconds in IJV group, 44.3 seconds in the IAX group, 46.1 seconds in the ISV group and 40.6 seconds in the SSV group. The access times were significantly shorter in the IJV group when compared with all the other three groups. The cannulation times for IJV in literature vary from 6 seconds to 45 seconds. This wide variation is mainly attributed to the definition of start and end points of the access time rather than the technique used. For example: ***Troianos and co-workers***[54] recorded the time between infiltration of local anesthetic and entry into the IJV, ***Denys and co-workers***[32] defined access time as the time between penetration of the skin and aspiration of venous blood into the syringe and we defined it as the time from the beginning of scanning until visualization of the tip of the needle inside the vein and free aspiration of blood.

The venous access times in all the other groups were significantly longer than in the IJV group of our study. The shorter time for IJV access indicates the ease of visualizing the vein using USG due to its superficial location and the better experience of the investigators in USG guided jugular venous access. Longer times for infraclavicular subclavian and axillary vein cannulations also indicates the difficulty in visualization of these veins due to the deeper location of the vessels & also the need to discontinue mechanical ventilation by disconnecting the patient from ventilator.

Even though the difference in access times were statistically significant, these differences may not be clinically significant except in emergency situations. Our study thus supports the use of IJV or SSV cannulation in emergency situations as suggested by others in literature[55].

CATHETERIZATION TIMES

Mean Catheterization times in our study was found to be 164.6 seconds in IJV group, 189.3 seconds in the IAX group, 186.72 seconds in the ISV group and 184.96 seconds in the SSV group. Like in venous access times, the catheterization time also can't be compared easily with reported literature due to the diversity in the definition of the catheterization time itself. ***Kocum et al***[56] in his study comparing three approaches to venous access in cardiac surgery patients reported catheterization times of 237±86 seconds for IJV approach, 213± 90 seconds for infraclavicular subclavian approach and 246± 86 seconds for supraclavicular subclavian vein catheterization. Our duration was lesser compared to their study which may be attributed to the use of USG guidance in our study. USG guidance have shown to decrease the catheterization times in various studies.

The catheterization time includes the additional time taken by us to demonstrate the guidewirein IJV or innominate vein (in case of infraclavicular subclavian vein or axillary vein). The studies of USG guided infraclavicular subclavian or axillary vein always mention about visualizing the guidewire in the cannulating vessel. We decided to demonstrate the guidewire in the brachiocephalic vein (using supraclavicular view) in addition to demonstrating it in the cannulating vessel when infraclavicular approaches were used. The advantage of this method is that catheter malposition (catheter going into ipsilateral IJV) can be minimized since the guidewire is already demonstrated in the brachiocephalic vein.We found that it is easier to demonstrate the guidewire in the brachiocephalic vein using a supraclavicular view than to demonstrate it in subclavian or axillary veinusing infraclavicular views. In thesupraclavicular view, guidewire can be easily seen traversing the subclavian vein and entering the brachiocephalic vein. We recommend this technique of demonstrating the guidewire in the brachiocephalic vein whenever an infraclavicular approach to central venous catheterization is undertaken.

CATHETER MALFUNCTION

Our definition of catheter malfunction was anything from loss of CVP trace to inability to aspirate blood from any of the ports. This variable was an important part of our study since a high incidence of catheter malfunctions has been reported in literature after sternal retraction in cardiac surgeries especially with infraclavicular subclavian approach. The incidence of catheter malfunction in our study was 14% in infraclavicular subclavian route and 8% in infraclavicular axillary route. None of the catheters in supraclavicular subclavian or internal jugular vein malfunctioned. The higher incidence of catheter malfunction in infraclavicular subclavian and infraclavicular axillary groups was statistically significant when compared to supraclavicular subclavian and jugular routes.

Higher incidence of catheter malfunction along with higher incidence of mechanical complications like pneumothorax is the primary reason for infraclavicular subclavian route falling out of favor in cardiac surgical patients. The close relation of first rib and the clavicle can lead to catheter kinking and malfunction and is described in literature as *'pinch off'* syndrome. ***Hinke et al***[57] first described this abnormality as catheter malfunction due to the mechanical forces i.e compression between first rib and clavicle in case of a subclavian line. He classified pinch off syndrome into four Grades ranging from normal smooth curved course of the catheter (Grade 0) to completely transected catheter (Grade 3) depending upon X-ray findings. All our patients with catheter malfunction had only low grades (Grade 0 or 1) of pinch off syndrome and the ports of the triple lumen catheter were functional after cessation of sternal retraction and chest closure.

The mechanical forces that compresses the catheter can get exaggerated after sternal retraction. The space bounded by clavicle, first rib, scalenus anterior and the costoclavicular ligament through which the catheter traverses can get further narrowed and distorted leading to catheter malfunction when infraclavicular subclavian venous access is used in patients undergoing cardiac surgery. The incidence of catheter malfunction is reported by ***Kocum et al***[56] to be as high as 21% in infraclavicular approach, 3% in supraclavicular approach, and none in jugular route. The consequences of catheter malfunction can range from inability to monitor the central venous pressure due to loss of trace, to serious problems including inability to give vasoactive agents which is frequently required in case of cardiovascular surgeries. None of our patients had malfunction of all the ports of the triple lumen catheter. Therefore, even when one of the ports malfunctioned, we were able to give vasoactive medications through alternative ports via infusion systems.

Use of axillary vein catheterization for cardiac surgical patients has not been reported. We found that when axillary vein catheterizations are used in cardiac surgery patients, the incidence of catheter malfunction after sternal retraction is 8%. . In our study we had similar rates of catheter malfunction in both the infraclavicular subclavian and infraclavicular axillary vein groups.

The occurrence of catheter malfunction in both infraclavicular subclavian and axillary vein catheterizations isclinically significant in patients undergoing cardiac surgery because the loss of monitoring of CVP and the inability to give vasoactive medications may have dire consequences unlike in other routine surgeries.

CATHETER MALPOSITION

There were only two instances of catheter malposition in our study, one in the jugular group where the catheter went into ipsilateral subclavian vein and one in the subclavian vein where it went into the ipsilateral jugular vein. The incidence of catheter malposition varies from 5.8% to 9.3% in upper body central venous access, more with subclavian vein cannulations. The higher incidence was seen when a catheter tip in RA was taken as a malposition. In our study we defined acceptable catheter position as any position of the catheter tip within 2 cm of SVC –RA junction or in the upper RA. There is continuing controversy on the correct position of the tip of the central venous catheter. ***Vesley***[58] in his article reviewed this controversy in detail and concluded that the ideal position is still debatable and the incidence of complications due to catheter tip in RA are rare. Some of the guidelines like **Kidney Disease Outcomes Qualiity Initiative (K/DOQI)**[59]Clinical Practice Guidelines for tunneled (cuffed) catheters states that the tip should be positioned at the SVC/ right atrial junction or into the right atrium to ensure optimal blood flow. In the "**Quality Improvement Guidelines for Central Venous Access**"[60] published in 1997 by Standards of Practice Committee of the Society of Cardio-vascular and Interventional Radiology define successful central line placement as *introduction of a catheter into the venous system with the tip in the desired location and the catheter functions for intended use* and thus leaves the tip placement at the discretion of the operator.

We decided on choosing either the SVC- RA junction or in the upper RA depending on the operator preference and accepted the upper RA as normal catheter tip position since it functions for the intended use and serves the purpose well.

Our protocol for demonstrating the guidewire entering the brachiocephalic vein might also have decreased the incidence of catheter malposition.

COMPLICATIONS

In our study we had 3 major mechanical complications, one pneumothorax (2%) and one inadvertent artery puncture in the infraclavicular subclavian approach and one arterial puncture in the axillary vein group. These results are similar to other studies published in literature.

The incidence of pneumothorax reported in literature ranges from 1.5 to 3.1% in subclavian approach, less than 0.4% in jugular approach[11,5].The incidence of pneumothorax in supraclavicular vein catheterization also is similarly low at less than 1%[44,56,61]. ***Buzancais et al***[38] in his study comparing infraclavicular subclavian and axillary vein catheterization found 3.3% incidence of pneumothorax in the subclavian group and no instances of pleural puncture or pneumothorax in the axillary vein group. These results are also similar to our study results.

The pleural puncture that occurred in our study immediately resulted in pneumothorax and was revealed by rise in airway pressures and decreased chest movements on that side and an ICD was inserted immediately preventing a progression to tension pneumothorax. A vigilant approach is needed when a procedure with potential for pneumothorax is being carried out like subclavian vein cannulation since clinical signs may be masked under drapes and early detection is imperative in preventing a tension pneumothorax and subsequent cardiovascular collapse in patients with labile hemodynamics.

The incidence of arterial puncture was also very low in our study, with one incidence of arterial puncture in the infraclavicular subclavian (2%) and one in the infraclavicular axillary vein group (2%). None of the patients in the jugular or the supraclavicular subclavian vein group had accidental arterial punctures. The reported incidence of arterial puncture duringattempted IJV catheterizations in literature ranges from 6.3 to 9.4% when USG is not used and between 1.4 to 1.7% when USG is used[5,11]. The infraclavicular subclavian vein approach without USGguidance has an accidental arterial puncture rate of 3.1 - 4.9%[61].

The use of ultrasound in subclavian vein catheterization has been controversial due to the lack of conclusive evidence for its efficacy for improving success. The meta-analysis on the use of ultrasound for subclavian venous access by ***Brass et al***[36] revealed no improvement in success rates or first attempt success rates with the use of USG guidance. However, they found a decrease in the incidence of inadvertent arterial puncture and hematoma formation with the use of 2D USG guidance. The French society while formulating guidelines on use of USG in central line access, analyzed the evidence for USG guidance in subclavian cannulationsand found a similar decrease in complications with the use of ultrasound.

Two different views are described for ultrasound guidance when used for vascular access, the long axis and the short axis views. Each has its own advantages and disadvantages and has to be chosen depending on operator's experience. Short axis views are easier to obtain, shows the relationship with the neighboring structures better, whereas the long axis views allow the needle to be kept in vision at all times minimizing the complications. ***Chittoodan et al***[62] when comparing short axis and long axis views for IJV cannulations in patients undergoing cardiac surgery has reported fewer number of needle passes and higher success rates with short axis view. The relative inexperience of their operators in long axis view for guidance was suggested as one of the reasons for the higher failures with that technique. We used short axis views for all approaches except supraclavicular subclavian access, where we used long axis view. Long axis views are easier to obtain than short axis view for supraclavicular subclavian vein. ***Vogue et al*** in a mannequin study for central venous catheterizations using long axis and the short axis views showed lesser needle redirections and lesser posterior wall punctures with the long axis views and suggested that long axis views may be associated with less complications. Our study shows that with careful use, the short axis views can be used safely with low complication rates.

SUMMARY AND CONCLUSIONS

SUMMARY AND CONCLUSIONS

We studied 200 patients in the age group between 18 and 80 years undergoing cardio-vascular surgery in our institute. This was a prospective, randomized study planned to compare the success rate, complication rate and time required for venous access and catheter insertion by 4 different routes including Internal jugular route, Infraclavicular axillary route, infraclavicular subclavian route and Supraclavicular subclavian route.
All the patients were randomly allocated into four groups with 50 patients in each group (IJV group, IAX group, ISV group and SSV group). All cannulations were done under real time ultrasound guidance.

The following conclusions were drawn from our study:

1. Internal jugular vein appears to be the best route for central venous access in cardiovascular surgical patients with high success rates, shortest access times and least incidence of mechanical complications.
2. Supraclavicular subclavian route is a viable alternative for these patients with similar success rates and complication rates as that of IJV.
3. Catheter malfunction due to sternal retraction is a potential problem in infraclavicular axillary and subclavian vein catheterization in cardiac surgery patients.
4. Ultrasound guidance should be considered in all routes of central venous access. Training and experience with the use of ultrasound decreases the

likelihood of complications, as evidenced by a low incidence of mechanical complications in our study.

5. Infraclavicular axillary vein can be used as an alternative where subclavian vein catheterization is planned with similar or even lesser complication rates.
6. It is easier to obtain long axis view of supraclavicular subclavian vein than short axis views.
7. We found that it is easier to demonstrate the guide-wire in the brachiocephalic vein using a supraclavicular view than to demonstrate it in subclavian or axillary vein using infraclavicular views. In the supraclavicular view, guide-wire can be easily seen traversing the subclavian vein and entering the brachiocephalic vein. We recommend this technique of demonstrating the guide-wire in the brachiocephalic vein whenever an infraclavicular approach to central venous catheterization is undertaken.

LIMITATIONS

LIMITATIONS

1. The catheterizations were done by more than one operator which may have confounded the results, although all the operators were trained and well experienced in ultrasound guided central venous accesses.
2. We limited the maximum number of attempts to three in any route before deeming the procedure as a failure and going for an alternate route or techniques. We limited the number of attempts in view of the higher mechanical complication rates when more than three attempts were used.
3. The short catheter stay in our study group makes our study not useful for studying the infectious or thrombotic complications.
4. The low incidence of mechanical complications makes this study unsuitable to compare these complications among the study groups. A study with much larger sample size may be needed to evaluate and compare such variables.

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ANNEXURES

Consent form

Title of study: COMPARISON OF FOUR ROUTES OF CENTRAL VEIN CANNULATION USING REAL TIME ULTRASOUND GUIDANCE IN CARDIOVASCULAR SURGICAL PATIENTS: A PROSPECTIVE RANDOMIZED STUDY

Study numbers: We request you to participate in the study where we are planning to evaluate the success rates of four different routes of central vein cannulation under ultrasound guidance cannulation in 200 patients undergoing cardiac and vascular surgeries.

What is central vein cannulation ?

Central vein cannulation means insertion of a small catheter inside one of the major veins in the body. This can be done blindly guided by landmarks or under ultrasound guidance, where you visualise the vein on the monitor and then insert the catheter.

Why is central veincannulation needed?

Central vein cannulation is required for various reasons like infusion of ionotropes and other irritant drugs, TPN which cannot be given through a peripheral cannula, measurement of central venous pressure which is a critical monitor in patients undergoing cardiovascular surgery. For these reasons, central vein cannulation is routinely performed for all cardiac surgical patients in our institute.

How and where is the cannulation done?

Central vein cannulation can be done through various routes. Each route has its own advantages and disadvantages and the site selection depend on lot of factors like type of surgery, presence of a coagulopathy, operator preference and so on. Here we are planning to study four different routes of cannulation, two in the neck and two in the upper chest wall.

How the cannula is put?

The procedure will be carried out after induction of general anesthesia with standard technique in the operation room. You will be monitored with an ECG, blood pressure and pulse- oximeter. You will be placed in supine position with 20-30° Trendelenburg tilt with a roll kept between the shoulders. The intended area including the neck and chest wall upto the level of nipple will be prepared with antiseptic solution (10% Povidone-Iodine solution) and sterile drapes will be used to provide maximum barrier precautions during the procedure. Depending on the route of cannulation selected the ultrasound probe will be placed and the corresponding vessel identified on the ultrasound monitor. The needle is then advanced seeing the tip of the needle on the monitor and the vessel is punctured. The successful puncture is identified by a free flow of blood into the syringe and the a guidewire is inserted into the vein through the needle. Then the needle is removed and the guidewire is again checked for its proper position using ultrasound. Then the dilator is used to dilate the vessel and catheter is subsequently introduced.

What are the risks and side-effects?

The risks of Central vein cannulation include mechanical complications like pneumothorax and hemothorax, infections, thrombosis of the cannulating vessel, catheter malpositions. The rate of complications vary depending on the route of cannulation like risk of pneumothorax is around 5-14% in Subclavian vein cannulation compared to 5- 10% in IJV cannulation, whereas the risk is only about 0-2% in both groups when ultrasound is used. Incidence of arterial puncture also varies between2-3% in IJV cannulation compared to 3-5% in SCV cannulation. This also comes down with ultrasound guidance to about less than 2% in both routes. The success rate also varies between 75 -85% in landmark technique when compared to 95 -100% success rates in ultrasound in both routes.

Why are we doing the study?

The results of the study will help to determine the usefulness of alternatives to Internal Jugular vein for central vein cannulation in patients undergoing cardiac surgeries. This will be useful to patients coming for sugery where an IJV cannulation is contraindicated or fails. It will also help to decide the best route of central vein cannulation in cardiac surgery patients.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will you have to pay for the study?

No.

Will your personal details be kept confidential?

The result of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However the medical notes will be reviewed by people associated with the study, without your permission, should you decide to participate in this study.

If you have any further questions, please ask:

Dr. Deepak Mathew Gregory, senior resident, Dept of anaesthesia (Tel: 8547801990) or mail me:deepakmg@sctimst.ac.inmailto:suddha@sctimst.ac.in

Dr. Prasanta Kumar Dash, professor, Dept of anaesthesia (Tel: 09349336584)

Dr.Rupa Sreedhar, professor, Dept of anaesthesia (Tel: 09446314043)

Dr. Shrinivas Gadhinglajkar, Professor, Dept of Anesthesia (Tel:09446304043 ***)***

DECLARATION

I, ____________________________________ (Please tick boxes)
•Participant's name: Date of Birth / Age (in years)
Declare that I have read the above information provided to me regarding the study:
COMPARISON OF FOUR ROUTES OF CENTRAL VEIN CANNULATION USING REAL TIME ULTRASOUND GUIDANCE IN CARDIOVASCULAR SURGICAL PATIENTS: A PROSPECTIVE RANDOMIZED STUDY
And have clarified any doubts that I had. [ ]

• I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]
• I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]
• I understand that my identity will not be revealed in any information released to third parties or published [ ]
• I voluntarily agree to take part in this study [ ]

• I received a copy of this signed consent form [ ]
Name:
Signature:
Date:
Name of witness:
Relation to participant:
Date:
(Person Obtaining Consent)

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

________________________________ ___________________

Name and Signature of Person Obtaining Consent

സമ്മതപത്രം

പഠനശീർഷകം

ഹൃദയശസ്ത്രക്രിയക്ക് വിധേയരാവുന്ന രോഗികളിൽ തത്സമയ അൾട്രാസൗ ിന്റെ ഗതിനിർണ്ണയത്തോടെ കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുന്ന നാല് മാർഗ്ഗങ്ങൾ തമ്മിലുള്ള താരതമ്യം ഒരു പഠനം

പഠനനമ്പർ

നാല് വ്യത്യസ്ഥ വഴികളിലൂടെ കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ അൾട്രാസൗ ിന്റെ ഗതിനിർണ്ണയത്തോടെ സൂചികടത്തുന്നതിന്റെ വിജയത്തിന്റെ തോത് വിലയിരുത്താൻ ഹൃദയ/ഉരസ്സ് ശസ്ത്രക്രിയക്ക് വിധേയരാവുന്ന 200 രോഗികളിൽ നടത്തുന്ന പഠനത്തിൽ പങ്കാളിയാകാൻ ഞങ്ങൾ താങ്കളോട് അഭ്യർത്ഥിക്കുന്നു.

കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുക എന്നാൽ എന്താണ്

ശരീരത്തിലെ പ്രധാന അശുദ്ധരക്തക്കുഴലുകളിലൊന്നിൽ ഒരു ചെറിയ കുഴൽ കടത്തുന്നതാണ് കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുക എന്നത്. ഇത് അന്ധമായി ദിശാസൂചികളുപയോഗിച്ചോ അൾട്രാസൗ ിന്റെ ഗതിനിർണ്ണയത്തോടെ മോണിറ്ററിൽ അശുദ്ധരക്തക്കുഴൽ ക ് അതിൽ കുഴൽ കടത്തുകയോ ചെയ്യാം.

കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുന്നതിന്റെ ആവശ്യം

അയണോട്രോപ്സും അതുപോലുള്ള അസ്വസ്ഥതയു ാക്കുന്ന മറ്റു മരുന്നുകളും കടത്തുക. റ്റിപിഎൻ ഒരു പുറമെയുള്ള സൂചിവഴിനൽകാനാവില്ല. ഹൃദയശസ്ത്രക്രിയാരോഗികളിൽ നിർണ്ണായകമായ കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിലെ മർദ്ദം അളക്കുക പോലുള്ള പല കാരണങ്ങളാൽ കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തേ ിവരുന്നു. ഈ കാരണങ്ങളാൽ നമ്മുടെ സ്ഥാപനത്തിലെ ഹൃദയശസ്ത്രക്രിയക്ക് വിധേയരാവുന്ന എല്ലാ രോഗികളിലും പതിവായി കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുന്നു.

എവിടെ എങ്ങിനെയാണ് സൂചികടത്തുന്നത്

കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുന്നതിന് വ്യത്യസ്ഥ മാർഗ്ഗങ്ങളു ്. ഓരോവഴിക്കും അതതിന്റേതായ നേട്ടവും കോട്ടവുമു ്. മാർഗ്ഗം തിരഞ്ഞെടുക്കുന്നത് ശസ്ത്രക്രിയയുടെ സ്വഭാവം, രക്തം കട്ടപിടിക്കാതിരിക്കൽ, ശസ്ത്രക്രിയാവിദഗ്ദ്ധന്റെ താത്പര്യം എന്നിങ്ങനെയുള്ള പല ഘടകങ്ങളെ ആശ്രയിച്ചാണ്. ഇവിടെ ഞങ്ങൾ നാല് വ്യത്യസ്ഥ വഴികളിലൂടെ സൂചികടത്തുന്നത്,- ര ണ്ണം കഴുത്തിലും, ര ണ്ണം നെഞ്ചിന്റെ മുകൾ ഭാഗത്തും -പഠിക്കുവാൻ ആസൂത്രണം ചെയ്യുന്നു.

എങ്ങിനെയാണ് സൂചികടത്തുന്നത്

ശസ്ത്രക്രിയാമുറിയിൽ സാധാരണമായ രീതിയിലുള്ള പൊതുവായ മയക്കൽ നടത്തിയിട്ടാണ് ഈ പ്രക്രിയ ചെയ്യുന്നത്. താങ്കൾ ഇസിജി, രക്തസമ്മർദ്ദംവും പൾസ് ഓക്സിമീറ്റർ എന്നിവയിലൂടെയുള്ള നിരീക്ഷണത്തിന് വിധേയനായിരിക്കും. താങ്കളെ ഊർദ്ധമുഖമായി 20-30 ഡിഗ്രി ടെന്റലൻബർഗ് ചരിവോടെ തോളുകൾക്കിടയിൽ ഒരു ചുരുൾവച്ച്കിടത്തും. കഴുത്തും നെഞ്ചിൽ മുലക്കണ്ണുംവരെയുള്ള ഉദ്ദേശിക്കുന്ന പ്രദേശം ആന്റി സെപ്റ്റിക് ലേപനം (10 പ്രൊവിഡോൺ-അയഡിൻ ലായനി) ഉപയോഗിച്ച് തയാറാക്കുകയും പ്രക്രിയക്കിടയിൽ അണുവിമുക്ത തുണിയുപയോഗിച്ചുള്ള പരമാവധി മുൻകരുതൽ നൽകുകയും ചെയ്യും. സൂചികടത്തുന്നതിനു തിരഞ്ഞെടുത്ത വഴിക്ക് അനുസരിച്ച് അൾട്രാസൗ ിന്റെ പ്രോബ് ഉപയോഗിച്ച് അൾട്രാസൗ ് മോണിറ്ററിൽ രക്തക്കുഴൽ ക ത്തുകയും ചെയ്യും. സൂചിയുടെ അഗ്രം മോണിറ്ററിൽക ുകൊ ് മുന്നോട്ടുകൊ ുപോയി രക്തക്കുഴൽ കിഴിക്കും. വിജയകരമായ ദ്വാരം സിറിഞ്ചിലേക്കുള്ള രക്തപ്രവാഹം വഴി തിരിച്ചറിഞ്ഞ് സൂചിയിലൂടെ ദിശാസൂചിയായകുഴൽകടത്തും. അതുകഴിഞ്ഞ് സൂചി മാറ്റി ദിശാസൂചിയായ കമ്പിന്റെ സ്ഥാനം കൃത്യമാണോയെന്ന് അൾട്രാസൗ ുപയോഗിച്ച് വീ ും പരിശോധിക്കും. എന്നിട്ട് രക്തക്കുഴൽ ഡയലേറ്ററുപയോഗിച്ച് വികസിപ്പിച്ച് കത്തിറ്റർകടത്തും.

എന്തൊക്കെയാണ് അപകടസാദ്ധ്യതയും പാർശ്വഫലങ്ങളും?

കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുന്നതിന്റെ അപകടസാദ്ധ്യതയിൽ ന്യൂമോതൊറാക്സ്, ഹീമോതൊറാക്സ് തുടങ്ങിയ യാന്ത്രിക സങ്കീർണ്ണതകളും, അണുബാധ, സൂചികടത്തിയ ര്കതക്കുഴലിലെ രക്തം കട്ടപിടിക്കൽ, കത്തീറ്റർ തെറ്റായ സ്ഥാനത്താവുകഎന്നിവയാണ്. സങ്കീർണ്ണതകളുടെ തോത് സൂചികടത്തുന്നതിന്റെ വഴിയെ ആശ്രയിച്ച് ന്യൂമോതൊറാക്സ് ഏകദേശം 5-14% സബ്ക്ലാവിയൻ അശുദ്ധരക്തക്കുഴലിലെ സൂചികടത്തലിലും, ഐജെവി സൂചികടത്തലിൽ 5-10% വും എന്നാൽ അൾട്രാസൗ ുപയോഗിച്ചാൽ ഏകദേശം 0-2% അപകടസാദ്ധ്യതയെ ര ുഗ്രൂപ്പിലും ഉ ാകൂ. ശുദ്ധരക്തക്കുഴലിലെ മുറിവും 2-3 ഐജെവി സൂചികടത്തലുമായി താരതമ്യത്തിൽ 3-5% എസ് സി വി ഐജെവി സൂചികടത്തലിലു ാകും. ഇതും അൾട്രാസൗ ുപയോഗിക്കുകയാണെങ്കിൽ ര ു മാർഗ്ഗത്തലും 2% എന്ന തോതിലേക്ക് താണുവരും. വിജയത്തിന്റെ തോതും ദിശാസൂചിയുപയോഗിച്ചുള്ള രീതിയിലെ 75-85% എന്നതിൽനിന്നും താരതമ്യത്തിൽ 95-100% വിജയം അൾട്രാസൗ ുപയോഗിക്കുമ്പോൾ ഉ ാകും.

ഞങ്ങളെന്തിന് ഈപഠനം നടത്തുന്നു.
ആന്തരിക ജൂഗുലാർ വെയിനിനുപകരം കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിലെ സൂചികടത്തലിന്റെ ഉപയോഗക്ഷമത നിശ്ചയിക്കുന്നതിൽ ഈ പഠനഫലം സഹായിക്കും. ഐജെവി സൂചികടത്തലിൽ പ്രശ്നമോ പരാജയമോഉ ാകുന്ന ശസ്ത്രക്രിയ്ക്കുവരുന്ന രോഗികൾക്ക് ഇത് ഗുണകരമാവും. ഹൃദയശസ്ത്രക്രിയാരോഗികളിൽ കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തഏറ്റവും നല്ല മാർഗ്ഗം തീരുമാനിക്കുന്നതിനും അതു സഹായിക്കും.

ആരംഭിച്ച ശേഷം ഈ പഠനത്തിൽ നിന്ന് പിന്മാറുവാൻ സാധിക്കുമോ?
ഈ പഠനത്തിൽ പങ്കെടുക്കുക എന്നത് നിങ്ങളുടെ മാത്രം തീരുമാനം അനുസരിച്ചാണ് ഇതിൽ പങ്കെടുക്കാതിരിക്കാൻ നിങ്ങൾക്ക് പൂർണ്ണ സ്വാതന്ത്ര്യമു ്. ആ തീരുമാനം നിങ്ങളുടെ ചികിത്സയെ ഒരു തരത്തിലും ബാധിക്കില്ല.

ഈ പഠനം മൂലം എന്തെങ്കിലും അപകടമു ായാൽ എന്തു സംഭവിക്കും?

അപകടം സംഭവിക്കാനുള്ള സാധ്യതയില്ല. എന്നാൽ തന്നെയും എന്തെങ്കിലും പാർശ്വഫലം ഉ ായാൽ യാതൊരുവിധ അധിക ചെലവുമില്ലാതെ അതിനുവേ ചികിത്സ നിങ്ങൾക്ക് ചെയ്തു തരുന്നതാണ്. പക്ഷെ അതിനു പകരമായി പണം തരുന്നതായിരിക്കില്ല.

പഠനത്തിന് രോഗി പണം കൊടുക്കേ തുേ ാ?

ഇല്ല

നിങ്ങളുടെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കുമോ?

ഈ പഠനത്തിന്റെ ഫലങ്ങൾ മെഡിക്കൽ പ്രസിദ്ധീകരണത്തിൽ പ്രസിദ്ധീകരിക്കും. പക്ഷെ ഒന്നിലും നിങ്ങളുടെ പേരോ അഡ്രസ്സോ പ്രസിദ്ധീകരിക്കില്ല. താങ്കൾ ഈപഠനത്തിൽ പങ്കടുക്കുകയാണെങ്കിൽ താങ്കളുടെ മെഡിക്കൽ വിവരങ്ങൾ ഈ പഠനത്തോട് ബന്ധപ്പെട്ട ആളുകൾ താങ്കളുടെ സമ്മതമില്ലാതെതന്നെ പരിശോധിക്കുന്നതായിരിക്കും.

നിങ്ങൾക്ക് ഇതിനെപ്പറ്റി കൂടുതൽ എന്തെങ്കിലും അറിയുവാനു െങ്കിൽ, ദയവു ചെയത് ഡോ. ദീപക് മാത്യു ഗ്രിഗറിയോട് (പ്രധാന ഗവേഷകൻ) ചോദിച്ചറിയുക. മൊബൈൽ ഫോൺ നമ്പർ : 8547801990 ഇ-മെയിൽ: deepakmg@sctimst.ac.in

ഡോ. പ്രശാന്ത കുമാർ ധാഷ്, പ്രൊഫസർ, ഡിപ്പാർട്ട്മെന്റ് ഓഫ് അനസ്തിഷ്യ (ഫോൺ. 09349336584)
ഡോ. രൂപാ ശ്രീധർ പ്രൊഫസർ, ഡിപ്പാർട്ട്മെന്റ് ഓഫ് അനസ്തിഷ്യ (ഫോൺ. 09446314043)

ഡോ. ശ്രീനിവാസ് ഗാദിൻഗ്ലജ്കർ പ്രൊഫസർ, ഡിപ്പാർട്ട്മെന്റ് ഓഫ് അനസ്തിഷ്യ (ഫോൺ. 09446304043)

പ്രഖ്യാപനം

ഞാൻ.. (വയസ്സ് / ജനനതീയതി).............മുകളിൽ വിവരിച്ചിരിക്കുന്ന കാര്യങ്ങൾ അറിഞ്ഞ് ബോധ്യപ്പെട്ടിരിക്കുന്നു.

(ബോക്സിനുള്ളിൽ (√) അടയാളപ്പെടുത്തുക).

ഹൃദയശസ്ത്രക്രിയക്ക് വിധേയരാവുന്ന രോഗികളിൽ തത്സമയ അൾട്രാസൗണ്ടിന്റെ ഗതിനിർണ്ണയത്തോടെ കേന്ദ്ര അശുദ്ധരക്തക്കുഴലിൽ സൂചികടത്തുന്ന നാല് വഴികൾ തമ്മിലുള്ള താരതമ്യം ഒരു പഠനം

- മുകളിൽ പറഞ്ഞിരിക്കുന്ന പഠനത്തെ കുറിച്ചുള്ള വിവരങ്ങൾ ഞാൻ വായിച്ചു മനസ്സിലാക്കി.
- എനിക്ക് ഉണ്ടായിരുന്ന സംശയങ്ങൾ ഞാൻ ചോദിച്ച് മനസ്സിലാക്കിയിട്ടുണ്ട്.
- ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് എന്റെ മാത്രം തീരുമാനമാണെന്നും എനിക്ക് എപ്പോൾ വേണമെങ്കിലും ഇതിൽ നിന്നും പിൻമാറാം എന്നും ഞാൻ മനസ്സിലാക്കുന്നു. അത് എന്റെ ചികിത്സയെയോ എന്റെ അവകാശങ്ങളേയോ ബാധിക്കുകയില്ലയെന്നും ഞാൻ മനസ്സിലാക്കുന്നു.
- ഞാൻ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും എന്റെ മെഡിക്കൽ റിപ്പോർട്ട് ഈ പഠനത്തിൽ ഏർപ്പെട്ട ഡോക്ടർമാർക്കും സ്ഥാപനത്തിലെ എത്തിക്സ് കമ്മറ്റിയിലെ അംഗങ്ങൾക്കും പരിശോധിക്കാൻ അവകാശമുണ്ട്. ഇതിനായി എന്റെ സമ്മതം ഞാൻ കൊടുക്കുന്നു.
- എന്റെ ഐഡന്റിറ്റി എവിടെയും വെളിപ്പെടുത്തുകയില്ല എന്നും ഞാൻ മനസ്സിലാക്കുന്നു.
- ഞാൻ പൂർണ്ണമനസ്സാലെ ഈ പഠനത്തിൽ പങ്കെടുക്കുവാൻ സമ്മതിക്കുന്നു.
- സംശയനിവാരണത്തിനായി പ്രധാന ഗവേഷകന്റെ ഫോൺ നമ്പർ എനിക്ക് നൽകിയിട്ടുണ്ട്.

പേര് :

ഒപ്പ് :

തീയതി :

സാക്ഷിയുടെ പേര് :
രോഗിയുമായുള്ള ബന്ധം :

ഒപ്പ് :

സമ്മതപത്രം ഒപ്പിടുവിച്ച വ്യക്തി
ഈ സമ്മതപത്രത്തിൽ ഗവേഷണത്തെപ്പറ്റിയുള്ള വിവരങ്ങൾ ആവശ്യാനുസരണം ഉണ്ട് എന്ന് ഞാൻ സ്ഥിരീകരിക്കുന്നു. രോഗിയോട് ഈ പഠനത്തെ കുറിച്ച് ലഘുവായ ഭാഷയിൽ വിവരിച്ച് കൊടുക്കുകയും അവരുടെ സംശയങ്ങൾ ദൂരീകരിക്കുകയും ചെയ്തിട്ടുണ്ട്. പഠനത്തിനിടയിൽ ഉണ്ടായേക്കാവുന്ന അപകടങ്ങളെപ്പറ്റിയും ദൂഷ്യഫലങ്ങളെപ്പറ്റിയും രോഗിയോട് വിവരിച്ചിട്ടുണ്ട്. സംശയങ്ങൾ ചോദിക്കുവാൻ പ്രോത്സാഹിപ്പിക്കുകയും അവ ദൂരീകരിക്കുകയും ചെയ്തിട്ടുണ്ട്.

പേര് :

ഒപ്പ് : തീയതി :

PROFORMA

Demographic data

- Age
- Sex
- Weight
- BMI

During the catheterization by all three methods following observation will be recorded by an independent observer:

- Number of attempts
- Success rate
- Venous access time*
- Catheterization time*
- Catheter malfunction during surgery*.
- Malposition*
- Complications
    - Local swelling /Skin haematoma
    - Subclavian/ Carotid artery puncture
    - Pneumothorax
    - Haemothorax

More than three attempts will be taken as a *failure.*

**Venous access time*is defined as the time from the beginning of scanning until visualization of the tip of the needle inside the vein and free aspiration of blood.

**Catheterization time*is defined as the time from the starting of insertion of the introducer needle to the end of catheter placement not including the suturing and fixation time.

**Catheter malfunction* is defined as any loss of CVP trace on the monitor or inability to aspirate blood freely from any of the three ports during surgery.

**Catheter malposition* defined as position of the tip of the catheter anywhere within 2 cms from the SVC - RA junction or in the upper RA.

In case of any accidental arterial puncture or pneumothorax, further attempts by the same approach was not undertaken and catheterization was done using alternate route.

Complications, if occurred will be managed according to the standard protocol.

LIST OF ABBREVIATIONS

CVC	-	Central Venous Catheter
CVP	-	Central Venous Pressure
ECG	-	Electrocardiography
FAST	-	Focused Abdominal Sonography in Trauma
IJV	-	Internal Jugular Vein
ISV	-	Infraclavicular Subclavian Vein
NICE	-	National Institute For Clinical Excellence
RA	-	Right Atrium
SSV	-	Supraclavicular Subclavian Vein
SVC	-	Superior Vena Cava
USG	-	Ultrasonography

TAC APPROVAL FORM

Technical Advisory Committee (Clinical Studies)

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2015/333 **Date:23.07.2015**

Project title: Comparison of four routes of central vein cannulation using real time ultrasound guidance in cardio-thoracic and vascular surgical patients– a prospective randomised study

Principal Investigator:
Name: Dr. Deepak Mathew Gregory Degree: M.D.(Anaesthesiology), M.B.B.S. Address: Senior Resident, Department of Cardiac Anaesthesiology, SCTIMST, Trivandrum.
Co-Principal Investigator(s)
(1) Name: Dr. Prasanta Kumar Dash Address: Professor, Department of Anesthesiology, SCTIMST, Trivandrum Degree: Post-Doctoral Certificate Course: Cardiothoracic Vascular and Neurosurgical Anesthesiology, M.D. (Anesthesiology), M.B.B.S.
(2) Name: Dr. Rupa Sreedhar Address: Professor, Department of Anesthesiology, SCTIMST, Trivandrum Degree: Post-Doctoral Certificate Course: Cardiothoracic Vascular and Neurosurgical Anesthesiology. D.N.B. (Anesthesiology), M.D. (Anesthesiology), D.A. (Anesthesiology), M.B.B.S.
(3) Name: Dr. Shrinivas Gadhinglajkar Address: Professor, Department of Anesthesiology, SCTIMST, Trivandrum Degree: Post-Doctoral Certificate Course: Cardiothoracic Vascular and Neurosurgical Anesthesiology. M.D. (Anesthesiology), M.B.B.S.

Members who participated in the TAC meeting on 04/07/2015
Dr. Sanjeev V Thomas (Chairman)
Dr. Asha Kishore
Dr. Lissy K Krishnan
Dr. Bejoy Thomas
Dr. Thomas Koshy
Dr. Krishnamoorthy.K.M
Dr. K. Shivakumar (Member Secretary)

Dr. Bejoy Thomas stayed away from the proceedings when the projects in which he was involved (#331, 335, 336, 343 and 344) as investigator were discussed.

Risk Classification of the project (Minimum/ Moderate/ High): Moderate
Requirement of DSMB: No
Recommended members of DSMB: Not applicable

Recommendations of TAC:
Recommended for consideration of IEC.

The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Signature of the Member Secretary, TAC (Clinical Studies)

Copy to IEC

1

IEC CLEARANCE FORM

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान

तिरुवनन्तपुरम - 695 011, केरल, भारत

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY

THIRUVANANTHAPURAM - 695 011, INDIA

(An Institute of National importance under Govt. of India)

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013)

SCT/IEC/810/AUGUST-2015 26-10-2015

Dr. Deepak Mathew Gregory
Senior Resident
Department of Cardiac Anaesthesiology
SCTIMST, Thiruvananthapuram

Dear. Dr. Deepak Mathew Gregory,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "COMPARISON OF FOUR ROUTES OF CENTRAL VEIN CANNULATION USING REAL TIME ULTRASOUND GUIDANCE IN CARDIO-THORACIC AND VASCULAR SURGICAL PATIENTS– A PROSPECTIVE RANDOMISED STUDY (IEC/810)" on 13th August, 2015.

The following documents were reviewed:

Original submission

1. *Covering letter addressed to the IEC, SCTIMST, dated 26.07.215.*
2. *TAC Approval Letter.*
3. *IEC application form.*
4. *Project Proposal.*
5. *Informed consent form in English and Malayalam.*
6. *CVs of PI and Co-PI.*

Revised submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 15.10.2015.*
2. *Copy of iEC Recommendation letter.*
3. *IEC application form.*
4. *Project Proposal.*
5. *Modified Informed consent form in English and Malayalam.*

Page 1 of 2

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E-mail : sct. @sctimst.ac.in
वेबसाइट
Website : www.sctimst.ac.in

The following members of the Ethics Committee were present at the meeting held on 13th August, 2015 at G. Parthasarathi Board Room, AMCHSS, SCTIMST.

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Justice Gopinathan. P.S	BSc. LLB	Male	Legal Expert (Chairperson)	No
2.	Dr. Asha Kishore	MD, DM	Female	Clinician (Neurologist)	Yes
3.	Shri. O.S. Neelakandan Nair	BE	Male	Engineer	Yes
4.	Dr. R V G Menon	PhD	Male	Lay Person	No
5.	Dr. Meenu Hariharan	DM	Female	Clinician (Gastro-Enterologist)	No
6.	Dr. M.D. Gupte	MD, DPH	Male	Public Health	No
7.	Dr. Rema M. N	MD	Female	Pharmacologist	No
8.	Dr. Kala Kesavan. P	MD	Female	Pharmacologist	No
9.	Dr. K R S Krishnan	ME, PhD	Male	Biomedical Scientist/Engineer	No
10.	Dr. Mala Ramanathan	MSc, PhD, MA	Female	Ethicist/Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

M Ramanathan

Mala Ramanathan
Member Secretary, IEC

PLAGIARISM CHECK

Deepak_thesis.docx

ORIGINALITY REPORT

2%

SIMILARITY INDEX

PRIMARY SOURCES

1	www.vascularaccessdoc.com Internet	49 words — 1%
2	Kocum, A.. "An Alternative Central Venous Route for Cardiac Surgery: Supraclavicular Subclavian Vein Catheterization", Journal of Cardiothoracic and Vascular Anesthesia, 201112 Crossref	22 words — < 1%
3	www.actaorthopaedica.be Internet	19 words — < 1%
4	citerahiadesgenettes.hautetfort.com Internet	17 words — < 1%
5	Brass, Patrick, Martin Hellmich, Laurentius Kolodziej, Guido Schick, Andrew F Smith, and Patrick Brass. "Ultrasound guidance versus anatomical landmarks for subclavian or femoral vein catheterization", Cochrane Database of Systematic Reviews, 2015. Crossref	16 words — < 1%

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EXCLUDE MATCHES OFF

AGE	SEX	WT	BMI	GROUP	ATTEMPTS	T can	T cath	malpos	malfn	compl	HNO
48	1	72	26.7	SSv	2	55	186	2	2	2	385971
69	2	63	25.9	SSv	1	33	148	2	2	2	393040
63	1	76	24.1	SSv	1	34	185	2	2	2	397524
63	1	61	23.9	SSv	2	44	205	2	2	2	390088
25	1	65	26.1	SSv	1	30	152	2	2	2	30476
78	1	71	24.2	SSv	1	61	232	2	2	2	399108
47	1	54	22.9	SSv	1	53	202	2	2	2	379956
62	1	68	24	SSv	1	33	153	2	2	2	402710
65	1	74	24.8	SSv	2	60	198	2	2	2	399676
30	2	45	21.1	SSv	1	33	146	2	2	2	398237
69	1	69	24.2	SSv	1	36	162	2	2	2	386725
52	1	52	21.6	SSv	2	50	216	2	2	2	366727
43	1	63	22.7	SSv	1	20	166	2	2	2	312080
51	1	64	22.2	SSv	1	24	172	2	2	2	385298
22	2	54	20.8	SSv	1	38	201	2	2	2	392155
65	2	63	21.4	SSv	1	41	208	2	2	2	408906
58	2	59	22.4	SSv	1	39	175	2	2	2	397033
15	2	41	20.2	SSv	1	44	182	2	2	2	398355
41	2	44	20.8	SSv	2	51	193	2	2	2	398763
63	2	52	21.2	SSv	1	47	208	2	2	2	389065
58	1	78	24	SSv	1	52	221	2	2	2	390001
48	2	62	22.6	SSv	1	43	195	2	2	2	410945
50	1	69	23.5	SSv	1	54	228	2	2	2	358565
69	1	71	24.2	SSv	1	61	231	2	2	2	299606
29	2	54	22.9	SSv	2	53	202	2	2	2	9801321
44	1	76	24.1	SSv	1	34	185	2	2	2	238376
71	2	48	19.7	SSv	1	44	205	2	2	2	397930
62	2	57	22.3	SSv	1	39	197	2	2	2	409510
58	1	84	26.3	SSv	1	31	186	2	2	2	394461
63	1	68	23	SSv	1	28	178	2	2	2	392822
74	1	63	25.8	SSv	2	41	164	2	2	2	397013
56	1	74	23.3	SSv	1	34	183	2	2	2	391304
61	1	71	26.1	SSv	1	23	144	2	2	2	388802
36	1	70	25.8	SSv	1	33	152	2	2	2	8806926
40	1	63	21.9	SSv	1	31	173	2	2	2	389212
64	1	69	25.6	SSv	1	22	161	2	2	2	398010
28	2	62	23.6	SSv	1	29	142	2	2	2	9409879
55	1	69	24.1	SSv	1	34	163	2	2	2	408928
62	1	71	23.4	SSv	1	33	184	2	2	2	412891
62	1	71	23	SSv	1	34	178	2	2	2	395325
49	1	69	23.1	SSv	1	31	181	2	2	2	412594
49	2	64	23.1	SSv	1	31	184	2	2	2	400579
56	1	67	23.2	SSv	1	26	174	2	2	2	397618
71	1	64	22.6	SSv	1	32	144	2	2	2	301453
65	1	64	22.4	SSV	3	136	270	2	2	2	404899
59	2	68	23	SSv	1	38	194	2	2	2	392289
58	2	63	22.1	SSv	1	44	188	2	2	2	406100
60	1	80	24.7	SSv	1	44	210	2	2	2	399980
53	1	68	23.2	SSv	1	38	194	2	2	2	391272
51	1	66	23.8	SSv	1	31	147	2	2	2	389316
54	1	53	21.5	IJV	2	55	186	2	2	2	395089
39	1	65	23.1	IJV	1	24	151	2	2	2	375190

29	2	59	22.2	IJV	1	24	148	2	2	2	392818
73	1	76	23.8	IJV	1	22	145	2	2	2	402425
48	2	71	23.8	IJV	1	21	155	2	2	2	395585
13	1	45	22.5	IJV	1	21	188	2	2	2	225334
44	1	66	22.9	IJV	1	22	136	2	2	2	238376
73	2	58	23.1	IJV	1	31	196	2	2	2	400336
54	2	62	24.1	IJV	1	22	138	2	2	2	390912
33	1	69	24.1	IJV	1	36	150	2	2	2	391919
64	1	68	23.2	IJV	1	26	196	2	2	2	397693
50	1	62	23.1	IJV	1	23	138	2	2	2	398233
45	1	73	25.5	IJV	1	22	153	1	2	2	408385
22	1	61	22.8	IJV	1	28	149	2	2	2	398784
52	1	74	24.7	IJV	1	30	154	2	2	2	405538
68	1	78	24.9	IJV	1	28	148	2	2	2	399134
52	1	61	24.1	IJV	1	21	152	2	2	2	396534
63	1	76	24.1	IJV	1	32	191	2	2	2	397359
63	1	69	23.8	IJV	2	43	158	2	2	2	305135
64	1	66	24.1	IJV	1	23	140	2	2	2	389065
55	2	66	23	IJV	1	26	158	2	2	2	391940
65	1	68	22.7	IJV	1	36	218	2	2	2	399505
56	1	66	23.1	IJV	1	37	186	2	2	2	9307891
56	1	68	22.7	IJV	1	24	156	2	2	2	403105
53	1	82	24.7	IJV	1	19	132	2	2	2	406500
66	1	66	23.2	IJV	1	35	158	2	2	2	411937
46	1	61	22.3	IJV	1	21	165	2	2	2	404341
51	1	72	23.9	IJV	1	20	172	2	2	2	409793
60	1	78	24.8	IJV	1	16	150	2	2	2	408905
58	1	68	22.7	IJV	1	27	188	2	2	2	357895
16	2	44	20.8	IJV	1	14	156	2	2	2	405002
55	1	67	22.9	IJV	2	38	195	2	2	2	397889
59		68	23.7	IJV	1	17	176	2	2	2	401829
55	2	69	23.3	IJV	1	18	144	2	2	2	396614
66	1	74	23	IJV	1	21	176	2	2	2	390973
74	1	69	22.9	IJV	1	23	176	2	2	2	397013
25	1	71	23	IJV	2	33	205	2	2	2	398758
77	1	68	23.2	IJV	1	22	136	2	2	2	384933
51	1	72	23.4	IJV	1	14	154	2	2	2	397366
40	2	57	21.2	IJV	1	18	143	2	2	2	339880
53	1	58	21.9	IJV	1	26	144	2	2	2	408033
62	1	78	24.8	IJV	1	21	200	2	2	2	397654
53	1	70	23.9	IJV	1	22	172	2	2	2	391472
67	1	72	23.8	IJV	1	17	201	2	2	2	389700
32	1	58	21.2	IJV	1	18	180	2	2	2	402924
47	1	47	24.1	IJV	1	15	145	2	2	2	413089
66	1	69	23.1	IJV	1	14	184	2	2	2	397556
33	1	68	23.2	IJV	1	20	170	2	2	2	403942
51	1	84	25	IJV	1	16	138	2	2	2	334854
22	1	48	23.5	IJV	1	38	180	2	2	2	390316
62	1	78	23.1	IAX	1	31	158	2	2	2	394594
69	1	71	24.3	IAX	1	38	164	2	2	2	397454
49	1	77	25.7	IAX	2	57	189	2	2	2	394862
64	2	80	24.9	IAX	1	27	163	2	2	2	417181
73	1	81	25.8	IAX	1	33	168	2	2	2	386598
52	1	76	24.5	IAX	1	30	153	2	1	2	397310
55	1	72	24.6	IAX	1	29	174	2	2	2	389678
48	1	71	23.8	IAX	2	55	199	2	2	2	396707
57	1	82	25.6	IAX	1	49	178	2	2	2	395810

62	2	69	23.1	IAX	1	38	165	2	2	2	381610
59	2	65	23.8	IAX	1	29	153	2	2	2	304706
60	1	81	23.6	IAX	1	44	164	2	2	2	390378
64	1	74	25.3	IAX	1	38	174	2	2	2	402765
58	1	72	24	IAX	1	38	195	2	1	2	384921
65	2	63	22.9	IAX	1	45	176	2	2	2	371875
48	1	69	23.7	IAX	1	28	132	2	2	2	389306
23	1	67	22.9	IAX	1	68	209	2	2	2	407061
59	1	61	22.8	IAX	1	54	226	2	2	2	401922
58	1	69	22.8	IAX	1	43	185	2	2	2	406280
16	1	42	23.1	IAX	1	51	247	2	2	2	371644
63	1	59	22.3	IAX	1	55	207	2	2	2	397515
64	2	64	23.9	IAX	1	75	339	2	2	2	380735
48	2	61	23.5	IAX	1	66	253	2	2	2	400459
27	2	52	23.6	IAX	1	44	229	2	2	2	398496
24	1	54	21.6	IAX	2	84	222	2	2	2	405095
58	2	56	23.4	IAX	1	42	198	2	1	2	406100
39	1	58	23.6	IAX	1	49	188	1	2	2	399283
47	2	59	22.8	IAX	1	33	139	2	2	2	400989
56	1	66	23.5	IAX	1	24	148	2	1	2	405142
69	1	78	23.2	IAX	1	47	204	2	2	2	392231
63	1	69	24.1	IAX	1	38	212	2	2	2	185494
61	1	78	23.2	IAX	1	47	204	2	2	2	391841
69	1	72	23.8	IAX	2	81	212	2	2	2	385710
61	2	59	23.8	IAX	1	38	190	2	2	2	390514
66	1	75	25.6	IAX	2	58	190	2	2	2	372979
52	1	70	23.1	IAX	1	39	166	2	2	2	406954
67	1	74	25.3	IAX	1	38	186	2	2	2	413958
47	1	78	23.5	IAX	1	36	168	2	2	2	408901
36	1	72	24.2	IAx	1	38	181	2	2	2	413704
65	1	79	24.9	IAX	1	35	158	2	2	2	375694
53	2	61	23.5	IAX	2	66	253	2	2	2	392883
60	1	52	21.6	IAX	1	44	229	2	2	2	393783
63	1	67	23.2	IAX	3	38	175	2	2	2	414707
63	1	77	25.1	IAX	FAIL		ART PUNCTURE				358789
68	1	76	23.1	IAX	FAIL					1	281645
71	F	65	23.8	IAX	FAIL						395168
50	1	71	24.5	IAX	FAIL						394602
43	1	72	23.9	IAX	1	35	169	N	2	2	384978
45	1	71	22.7	IAX	1	30	159	2	2	2	403109
58	2	65	23.4	IAX	1	33	158	2	2	2	393276
70	2	54	20.4	ISV	1	34	214	2	2	2	413670
33	1	70	22.6	ISV	1	32	141	2	2	2	410661
53	1	81	25	ISV	1	65	209	2	2	2	408033
58	2	59	21.4	ISV	3	113	208	2	1	2	405403
49	2	58	23.2	ISV	1	49	216	2	2	2	396137
50	1	80	24.7	ISV	3	101	222	2	1	2	409700
75	1	69	23.6	ISV	1	76	208	2	2	2	390595
33	2	63	22.6	ISV	1	67	199	2	2	2	326740
63	1	72	23.1	ISV	1	45	207	2	2	2	397359
49	1	72	22.4	ISV	1	54	205	2	2	2	389054
73	1	64	22.6	ISV	3	88	265	2	2	2	244076
31	1	50	20.6	ISV	1	38	206	2	2	2	409528
47	1	60	22.2	ISV	1	44	180	2	1	2	393173
32	2	54	21.9	ISV	1	39	206	2	2	2	41080
56	1	54	20.9	ISV	1	38	139	2	2	2	406796
68	1	51	21.1	ISV	1	48	186	2	2	2	387248

50	2	54	21.2	ISV	1	38	197	2	2	2	399334
45	1	69	23.2	ISV	1	41	205	2	1	2	403345
61	2	60	21.7	ISV	1	40	196	2	2	2	385994
54	1	67	22.4	ISV	2	84	235	2	2	2	405287
15	2	40	20.8	ISV	2	91	216	2	2	2	400375
58	1	78	24.2	ISV	FAIL						396177
54	1	72	25.8	ISV	FAIL			Y ART PUN		1	369818
59	1	69	24.5	ISV	1	33	174	2	2	2	409857
59	1	76	26.3	ISV	1	34	178	2	2	2	400758
74	1	71	24.5	ISV	1	41	179	2	2	2	386979
76	1	74	25.2	ISV	2	51	178	2	1	2	388574
72	1	81	26.4	ISV	1	32	170	2	2	2	384127
53	1	69	24.1	ISV	2	37	173	2	2	2	387557
48	2	58	21.6	ISV	1	33	168	2	2	2	393188
38	1	62	21.8	ISV	1	29	158	2	2	2	222782
59	2	68	23.5	ISV	1	22	150	2	1	2	391379
38	1	52	21.6	ISV	1	28	176	2	2	2	366729
57	1	58	22.9	ISV	1	29	154	1	2	2	393532
64	1	66	22.7	ISV	1	26	176	2	2	2	383764
34	2	60	21.8	ISV	1	31	164	2	2	2	411972
36	1	62	22.4	ISV	1	36	154	2	2	2	396963
43	1	56	21.7	ISV	1	36	184	2	2	2	396353
27	1	52	20.8	ISV	1	41	164	2	2	2	398496
65	1	63	21.6	ISV	1	44	176	2	2	2	399505
58	2	65	23.8	ISV	1	44	188	2	2	2	406100
59	2	66	24.3	ISV	FAIL						390903
65	1	69	23.1	ISV	1	39	168	2	2	2	402394
65	1	72	26.1	ISV	1	40	175	2	1	2	410327
55	1	73	25.4	ISV	1	41	183	2	2	2	400170
42	2	69	23.7	ISV	1	33	178	2	2	2	406112
54	1	73	25.7	ISV	1	37	164	2	2	2	408437
58	1	77	26.1	ISV	2	52	191	2	2	2	403717
61	1	72	25.8	ISV	1	35	175	2	2	2	406916
67	1	78	23.5	ISV	1	48	218	2	2	2	410183