Editorial

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The SIF protocol: A seven-step strategy to minimize complications potentially related to the insertion of femorally inserted central catheters

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Fabrizio Brescia[1], Mauro Pittiruti[2], Matthew Ostroff[3], Timothy R Spencer[4] and Robert B Dawson[5]

Abstract

The insertion of central venous catheters through the femoral veins is not uncommon and is potentially associated with the risk of immediate puncture-related complications and severe late complications as infection and thrombosis. As for other central venous access devices, the use of a standardized protocol of insertion and the correct application of evidence-based strategies are beneficial in reducing the risk of complications. We proposed a standardized protocol (S.I.F.: Safe Insertion of Femorally Inserted Central Catheters) consisting of seven strategies that should be part of vascular cannulation and should be adopted during the insertion of femoral venous catheters, aiming to minimize immediate, early and late insertion-related complications. These strategies include: preprocedural evaluation of the patient history and of the veins, appropriate aseptic technique, ultrasound guided puncture and cannulation of the vein, intra-procedural assessment of the tip position, adequate protection of the exit site, proper securement of the catheter, and appropriate coverage of the exit site.

Keywords

Techniques and procedures, ultrasound guidance, standardized assessment, central venous access, patient safety, femorally inserted central catheters

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Introduction

The insertion of Femorally Inserted Central Catheters (FICC) is a common procedure in clinical practice, as it represents an alternative site for central venous access in patients who have relative or absolute contraindications to the insertion of peripherally inserted central catheters (PICC) and centrally inserted central catheters (CICC). Placement of an FICC requires venipuncture of a vein in the inguinal region (common femoral vein—CFV or superficial femoral vein—SFV) and the tip of the catheter is usually placed in the inferior vena cava. Typical conditions requiring FICCs include: (a) cancer patients with obstruction of the superior vena cava (SVC) requiring chemotherapy; (b) complex vascular access patients with venous thrombosis and/or pre-existing central lines in the tributaries of SVC; (c) trauma patients and other hypovolemic patients during emergency venous cannulation who require immediate venous access for volume repletion and resuscitation; (d) acute renal failure patients with difficult or impossible insertion of non-tunneled dialysis catheter in

[1]Unit of Anesthesia and Intensive Care Medicine, Vascular Access Team, Centro di Riferimento Oncologico di Aviano, IRCCS, Aviano, Italy
[2]Department of Surgery, Fondazione Policlinico Universitario "A. Gemelli" IRCCS, Rome, Italy
[3]Saint Joseph's University Medical Center, Paterson, NJ, USA
[4]Global Vascular Access, LLC, Scottsdale, AZ, USA
[5]DNP, MSA, APRN, ACNP-BC, VA-BC Hospital Medicine and Vascular Access, Catholic Medical Center—Upper Connecticut Valley Hospital, Colebrook, NH, USA

Corresponding author:
Fabrizio Brescia, Unit of Anesthesia and Intensive Care Medicine and Vascular Access Team, Centro di Riferimento Oncologico di Aviano, IRCCS, Via Gallini 2, Aviano 33081, Italy.
Email: fabriziobrescia@gmail.com

the supraclavicular area; (e) intensive care patients who may have difficult or impossible PICC or CICC insertion because of pathologic alterations of the upper limbs and of the cervico-thoracic area (burns, extensive surgery, other); (f) non-collaborative patients with cognitive disorders who may benefit of a FICC because of the high risk of accidental removal of PICCs and CICCs.

As for any central venous access, the safety of FICC insertion has improved, mainly because of the increasingly widespread use of ultrasound guidance. Ultrasound is also useful for preliminary assessment of femoral veins, for immediate detection of possible puncture-related complications (such as tissue hematomas, intramural hematomas of the vein, other) and—especially in pediatric patients—also for "tip navigation" (i.e. to verify the correct direction of the guidewire and/or catheter while they progress into the vascular system) and for "tip location" (i.e. to assess the central position of the tip). Finally, ultrasound plays a major role in the diagnosis of many late non-infective complications (fibroblastic sleeve, catheter-related venous thrombosis, other).[1–3]

Besides ultrasound, there are other evidence-based strategies that increase the safety and the cost-effectiveness of the procedure (correct choice of exit site, skin antisepsis with 2% chlorhexidine in alcohol, maximum barrier precautions, sutureless securement, other).[4] An insertion bundle consists of clear recommendations based on scientific evidence, capable of acting synergistically to provide maximal safety, positive outcomes, and cost-effectiveness of a given procedure. When placing a FICC, the purpose of an insertion bundle is to minimize all complications directly or indirectly related to the maneuver (accidental injury, incorrect tip location, catheter-related venous thrombosis, catheter-related infections, other).

A similar insertion bundle has already been proposed for peripherally inserted central catheters and for centrally inserted central catheters, the so-called SIP protocol and SIC protocol.[5,6] In the following paragraphs, the authors propose a bundle for minimizing insertion-related complications associated with FICC, the "SIF" protocol (Safe Insertion of Femoral Catheters). It consists of seven different steps which summarize those evidence-based recommendations that, if applied correctly and systematically, may help to achieve a safe, successful, and cost-effective procedure (Table 1).

Table 1. The seven steps of the SIF Protocol.

Step 1	*Preprocedural evaluation*—choice of the vein by systematic ultrasound examination of the veins of the groin and the thigh (RaFeVA protocol) and choice of the ideal exit site (Femoral ZIM)
Step 2	*Appropriate aseptic technique*—hand hygiene, skin antisepsis with 2% chlorhexidine in 70% alcohol, maximal barrier precautions
Step 3	*Ultrasound-guided insertion*—ultrasound-guided venipuncture, ultrasound verification of the correct direction of the guidewire (tip navigation)
Step 4	*Intra-procedural assessment of tip location*—if the tip must be in IVC, use length estimation by anthropometric measurement and consider post-procedural x-ray; if the tip must be in RA or at IVC/RAJ, use intracavitary ECG and/or by transthoracic echocardiography (in subcostal view, using the "bubble test")
Step 5	*Adequate protection of the exit site*—reduction of the risk of bleeding and risk of contamination by sealing with cyanoacrylate glue
Step 6	*Proper securement of the catheter*—stabilization of the catheter using skin-adhesive sutureless devices, transparent dressing with integrated securement, or subcutaneous anchorage
Step 7	*Appropriate coverage of the exit site*—semi-permeable transparent dressing, preferably with high breathability

Preprocedural evaluation: The Rapid Femoral Vein Assessment (RaFeVA) and the Femoral Zone Insertion Method (Femoral ZIM)

Proper pre-procedural evaluation obviously begins with an adequate anamnestic evaluation. It is important to consider whether the patients had previous vascular devices or repeated difficult venipunctures. Also, it is important to evaluate the patient's coagulation and platelet status, although the incidence of major bleeding complications after central venous catheter placement is low, even in coagulopathic patients,[7] as well as ensuring that there is no contamination or infection in the groin area or positive surveillance rectal swab for multidrug-resistant germs; in the latter case the opportunity for access to the femoral region should be reconsidered, balancing risks and benefits. The presence of Candida colonization at the groin (particularly frequent in intensive care patients) may be an absolute contraindication to CFV access and a relative contraindication to SFV access.

Before starting the procedure, two important issues of concern are the selection of the appropriate vein and the location of the exit site of the catheter.

The choice of the vein must be carefully considered before proceeding with FICC insertion. A rational and objective systematic evaluation of the anatomical characteristics of the vascular system of each patient is possible through the adoption of a pre-procedural ultrasound scan of the groin and of the thigh.[8,9]

The Rapid Femoral Vein Assessment protocol (RaFeVA) is a rapid and effective tool for a systematic ultrasound evaluation of the veins at different levels of the lower limb, from the groin to the middle of the thigh, with the aim of choosing the best approach and the best location for positioning of different types of FICC.[8] The RaFeVA was based upon the concept of RaCeVA (Rapid Central Vein Assessment)[9] and designed for an easy, rapid, and systematic assessment of

the common femoral vein (CFV) and of the superficial femoral vein (SFV), so that the operator may rule out venous abnormalities such as thrombosis, stenosis, external compression, anatomical variations of size and shape of the veins, choose an appropriate catheter/vein ratio (ideal 1:3 or less) so to reduce the risk of catheter-related thrombosis and obtain a full anatomic evaluation for optimum site selection and the best insertion approach for each patient.[1] The appropriate catheter/vein ratio is particularly relevant when using the CFV approach for large bore catheters for hemodialysis, potentially associated with high risk of catheter-related thrombosis. RaFeVA also visualizes the surrounding arterial structures that could be accidentally injured during venous catheterization.[8]

The large caliber and easy localization of common femoral vein (CFV), even in patients with severe hypovolemia, make this venous access site very convenient in emergency situations or for acute dialysis catheters. Though, when non-tunneled catheters are inserted in the CFV, the exit site is in an unfavorable anatomical location, at the groin level, that is, in a flexion area (which presumably increases the risk of catheter-related venous thrombosis—CRT)[10,11] and in a region exposed to high bacterial contamination, especially in bedridden patients (which increases the risk of catheter-related bloodstream infections—CRBSI).[2] For these reasons, the common femoral venous access should be used mainly for emergency short-term infusions or short-term hemodialysis (non-tunneled FICC), unless it may be possible to tunnel the catheter so to move the exit site in an appropriately safe area, far from the inguinal crease.

This protocol suggests the opportunity of applying Dawson's Zone Insertion Method (ZIM) for Peripherally Inserted Central Catheters (PICCs)[12] to the lower limb region (so-called "Femoral ZIM"). As in the arm, the groin and the thigh may be divided in three different zones, *red, yellow, and green*, that correspond to the groin, upper third of the thigh and mid-thigh (Figure 1(a)).

The *red zone* is an area with high bacterial contamination of the skin, due to the proximity to the genitourinary region. It is also an area with high risk of catheter dislodgment because of the movements of the lower limb. For this reason, an exit site in the groin area should be avoided as much as possible and—if inevitable—the FICC should be removed as soon as possible. A non-tunneled FICC in the CFV with exit site at the groin, if placed in emergency conditions, should be removed as soon as possible[13]; there are no clear recommendations about the timing of removal of a dialysis catheter inserted in the CFV, though the KDOQI guidelines released in 2020[14] suggest that a non-tunneled dialysis catheter should also be removed as soon as possible.

The *yellow zone* corresponds to the upper third of the thigh area, where ultrasound (US)-guided venipuncture of CFV is feasible and easy. An exit site in the upper third of the thigh area is acceptable but not always ideal. Even in this case, tunneling the catheter—so to move the exit site to a safer area—is recommended.

Tunneling is a strategy providing both an optimal insertion site and an optimal location of the exit site.[15–21] The strategy of moving the exit site far from the puncture site reduces the risk of extraluminal bacterial contamination and of catheter dislodgment. As regards to FICCs, two main types of tunneling are useful: tunneling the catheter upward (retrograde) to the abdomen (tunneling type A) (Figure 1(b)) or downward (anterograde) to the mid-thigh (tunneling B) (Figure 1(c)). The latter might be indicated, for example, in the population of non-cooperative patients with cognitive disorders in whom involuntary catheter dislocation is quite common (tunneling the catheter places the exit site out of reach of the patient's hands), or in critically ill patients with severe respiratory disorders, especially if treated by pronation.[22–24]

The *green zone* corresponds to the mid-thigh area, where US-guided venipuncture of SFV is usually feasible.[25–27] An exit site in the mid-thigh area carries a low risk of bacterial contamination and low risk of dislodgment.[8]

For the tunneling of the catheter, it is preferable to use blunt tunnelers, as they are associated with minimal risk of local bleeding even in patients with coagulation disorders or with reduced platelet counts.[28]

In short, RaFeVA permits clinicians to choose the optimal venipuncture site while the Femoral ZIM compliments RaFeVA to plan the optimal exit site.

Appropriate aseptic technique

The second very important step concerns the aseptic technique to be used during insertion. Hand hygiene must be preferably performed with hydroalcoholic gel. In special cases, or when the hands are visibly dirty, the hydroalcoholic gel must be preceded by washing with soap and water, in accordance with current international guidelines of infection prevention. For skin antisepsis, 2% chlorhexidine in 70% isopropyl alcohol should be used: iodine povidone in alcohol has a role only in case of known allergy or sensitivity to chlorhexidine. Regarding the antiseptic application technique, no clinical difference in microorganism reduction between the concentric circle and the back-and-forth techniques has been documented, both techniques should be used equally on clean and healthy skin.[29] As recommended for any insertion of central venous access devices, maximal barrier precautions should be adopted (non-sterile cap, non-sterile mask, sterile gown, sterile gloves, full-size sterile drape over the patient, plus adequate sterile protection of the ultrasound probe).[2,30] If such strategies are not fully adopted (as it may happen for a FICC inserted in the emergency room), the device must be removed as soon as possible and no later than 24 h.[12]

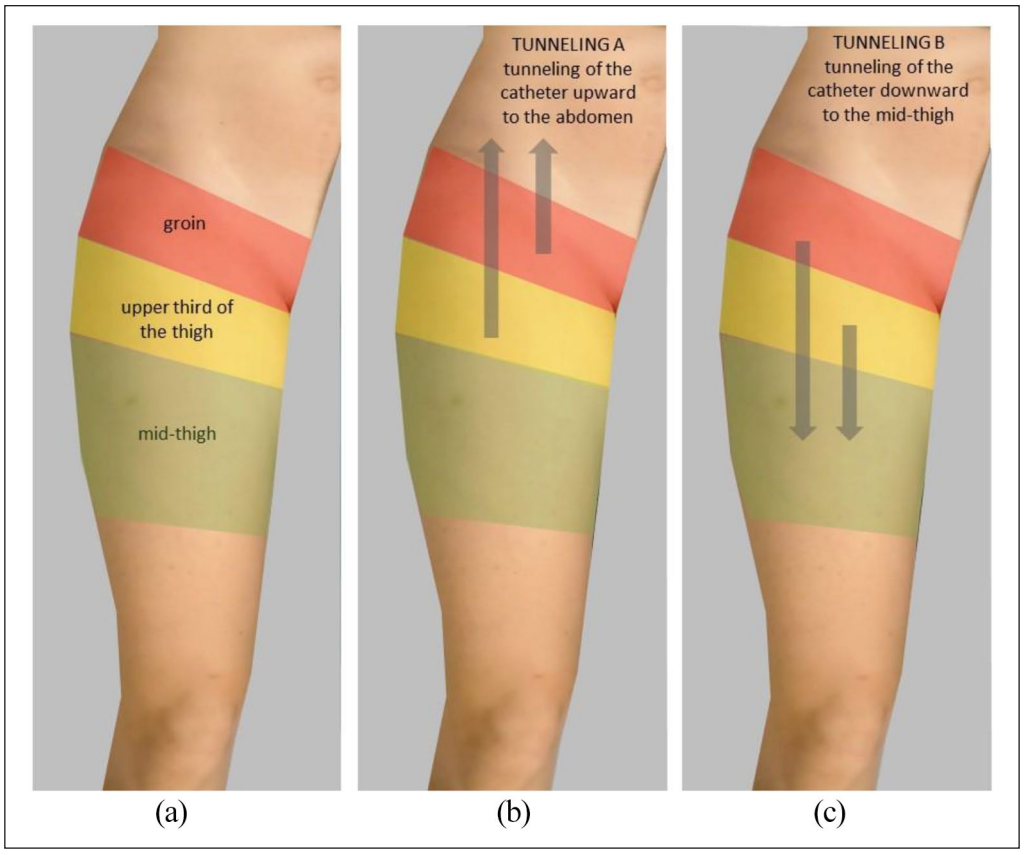

Figure 1. (a) Femoral Zone Insertion Method (Femoral ZIM), (b) tunneling of the catheter upward to the abdomen (retrograde), and (c) tunneling of the catheter downward to the mid-thigh (anterograde).

Ultrasound-guided insertion

Ultrasound-guided venipuncture is considered mandatory for all central venous catheterizations.[1,2] It significantly reduces early mechanical complications, late infectious and thrombotic complications, the number of attempts and the overall cost of the maneuver, not only for PICCs and CICCs, but also for FICCs insertion.[31] A recent guideline[1] suggests that the benefits of US guidance documented for CFV can be extended also to SFV.

In the groin and the upper third of the thigh, the CFV can be accessed by ultrasound guidance, with two different techniques: vein visualization in short axis with out-of-plane puncture, or visualization in long axis with in-plane technique.[8]

In the mid-thigh area, the SFV can be visualized either in short axis or in oblique axis. Depending on the level of the thigh, the rotation of the limb, and possible anatomic variants, the SFV may be placed laterally, medially or below the superficial femoral artery (Figure 2).[8,25] If the SFV is not below the artery, a short axis, out-of-plane approach may be adopted. The oblique axis view is obtained rotating the probe to almost halfway between the

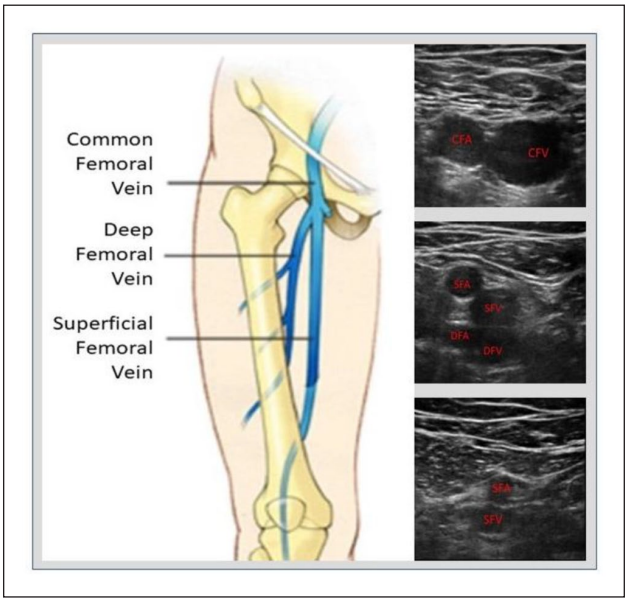

Figure 2. Femoral vein and ultrasound assessment.
CFV: common femoral vein; DFV: deep femoral vein; SFV: superficial femoral vein; CFA: common femoral artery; DFA: deep femoral artery; SFA: superficial femoral artery.

short axis and the long axis view. This oblique axis visualization allows to maintain a panoramic view of the surrounding structures (arteries and nerves), making it possible to perform a safe in-plane puncture, particularly when the SFV is located just below the superficial femoral artery.[25] The oblique axis + in-plane technique combines the advantages of the panoramic view with the optimal visualization of the needle tip during its trajectory.[32,33]

The authors recommend the use of a micro-introducer kit consisting of a 21 Gauge echogenic needle (for minimally invasive venipuncture), a 0.018″ nitinol guidewire with straight soft tip, and a micro-introducer/dilator, for both CFV venipuncture and SFV venipuncture, since this is associated with reduced local trauma.[6] Some cases of venipuncture of the SFV, especially in patients with high BMI, when the vein is located at a depth of 5–6 cm, may require long needles and long micro-introducer-dilators.[25]

Soon after the US-guided venipuncture, ultrasound should also be used for assessing the correct direction of the guidewire while it progresses into the vascular system (US-based "tip navigation"). This maneuver can be performed with the same linear probe used for venipuncture, usually visualizing the CFV in long axis. It is advisable to record and document the ultrasound images in the medical record.

Intra-procedural assessment of tip location

The fourth important step of the SIF bundle is the intraprocedural assessment of the position of the tip ("tip location"). Intra-procedural control of tip location is preferred to post-procedural control,[2] since the latter is associated with inefficiencies in procedural time and resources, as well as potential harm to the patient. As regards FICCs, there are no clear recommendations in the literature about the ideal location of the tip or about the most appropriate method of tip location. The tip of the FICC can be placed either in the Inferior Vena Cava (IVC) or in the right atrium (RA) or at the junction between IVC and RA (IVC/RAJ). When the tip is in IVC, the FICC can be used for administering any type of infusion (including vesicant or irritant drugs), for dialysis, and for blood sampling. When the catheter tip is in RA or at IVC/RAJ, the FICC can be additionally used for hemodynamic monitoring.[25]

When the tip of the FICC is expected to be in the IVC, length estimation by anthropometric measurement is useful. In adult patients, 25 cm from the inguinal sulcus corresponds to the location in IVC. Undesired and potentially dangerous positioning of the tip includes (a) the iliac veins (risk of venous thrombosis and catheter malfunction), (b) the median lumbar vein and the right or left ascending lumbar veins (risk of persistent withdrawal occlusion, venous thrombosis, lumbar pain), (c) the renal veins (risk of venous thrombosis), and (d) the hepatic veins. The latter location is particularly dangerous since it is associated with a very high thrombotic risk.[34,35] The most appropriate intra-procedural method of ultrasound-based verification of the presence of the tip in the ideal portion of the IVC (above the iliac veins and below the renal veins) is still to be defined. Intraprocedural and post-procedural radiological methods of tip location (fluoroscopy and x-ray of the abdomen) may be useful though they are not accurate, as they are based on relatively uncertain radiological landmarks.

Regarding FICCs with the tip in RA or at the IVC/RAJ, the most cost-effective and accurate intra-procedural method for tip location is intracavitary electrocardiography (IC-ECG).[36–39] Fluoroscopy is an acceptable intraprocedural method, but is often inaccurate, expensive, logistically difficult, and even unsafe as it exposes patients and operators to unnecessary ionizing radiation.[2] When intracavitary ECG is not applicable or not feasible, another effective, inexpensive, and non-invasive intraprocedural method for tip location is transthoracic echocardiography (TTE): RA and IVC/RAJ are well visible by ultrasound in subcostal view, with convex or sectorial probe; the "bubble test" (a rapid infusion of a few milliliters of "agitated" saline solution) allows for better visualization of the catheter tip.[40–42]

Adequate protection of the exit site

At the time of FICC insertion, an appropriate strategy for protection of the exit site from bleeding and from extraluminal bacterial contamination is cyanoacrylate glue: this becomes particularly relevant when the exit site is at the groin, that is, in a skin area at very high risk of contamination. Glue may also reduce "micro-movements" of the catheter at the exit site, reducing local damage to the endothelium of the vein, potentially reducing the risk of thrombosis.[43] The authors recommend using glue only at the time of insertion; at the first dressing change, antibacterial protection of the exit site will be ensured using chlorhexidine-impregnated sponge dressing.[44] In the case of tunneling, glue will also be used for closing the skin at the site of venipuncture and tunneling puncture points.

Proper securement of the catheter

Securement by sutures is discouraged by all current guidelines.[2] Suture-based securement of venous access devices is associated with a high risk of exit-site infection and catheter dislodgment, as well as the risk of accidental needlestick puncture for the operator. Current alternative options for securement are skin-adhesive sutureless devices, transparent dressing with integrated securement, and subcutaneous anchorage. In any patient at high risk for catheter dislodgment (cognitive disorders, skin abnormalities, relevant perspiration, other), it is advisable to use a subcutaneously

anchored sutureless device. Subcutaneously anchored securement is apparently safer and more effective than skin-adhesive devices. It is also theoretically associated with less risk of infection since it allows a more complete skin antisepsis around the exit site.[45–47] Considering the high risk of dislodgment of FICCs, the authors recommend considering subcutaneous anchorage as the preferred option in medium- or long-term femoral access.

Exit site coverage

The exit site should always be covered with a semi-permeable transparent dressing—preferably with a high breathability factor—so to ensure adequate protection of the exit site and stabilization of the catheter.[30]

Appropriate catheter securement and appropriate protection of the exit site are key factors for reducing the incidence of dislodgment, infection, and venous thrombosis.

Conclusions

The SIF protocol consists of seven strategies which, if applied correctly, could minimize the complications potentially related to FICC insertion, either immediate, early, or late. Among these safe strategies, as documented for other types of central access as PICCs and CICCs,[4–6] the use of ultrasound plays a fundamental role in different phases of the maneuver (choice of the vein, venipuncture, tip navigation of the guidewire, tip position, other). The use of standardized protocols for the choice of the vein (RaFeVA) and the exit site (Femoral ZIM), as well as the adoption of adequate measures for the prevention of infections (hand hygiene, effective skin antisepsis with chlorhexidine 2% in 70% isopropyl alcohol, maximum sterile barrier precautions), the correct evaluation of the FICC tip position and a correct stabilization and protection of the exit site—as documented for PICC and CICC insertion—would also help to achieve a successful and safe procedure.

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ORCID iDs

Fabrizio Brescia https://orcid.org/0000-0002-6892-474X
Mauro Pittiruti https://orcid.org/0000-0002-2225-7654
Matthew Ostroff https://orcid.org/0000-0001-5417-5621
Timothy R Spencer https://orcid.org/0000-0002-3128-2034

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