


ORIGINAL ARTICLE

Open Access



Safety of sheathless vascular access using braided 4 F selective catheters for common body interventions – a retrospective study

Jonathan Nadjiri* , Tobias Geith, Marc Mühlmann, Tobias Wagershauser and Philipp M. Paprottka

Abstract

Background Besides other factors, complication rate of transarterial interventions depends on the size of the vascular access. Therefore, the vascular access is mostly chosen as small as possible while still allowing all planned parts of the intervention.

This retrospective analysis is to evaluate the safety and feasibility of sheathless arterial interventions for a broad spectrum of interventions in daily practice.

Methods All sheathless interventions using a 4 F main catheter between May 2018 and September 2021 were included in the evaluation. Additionally, intervention parameters such as type of catheter, use of microcatheter and required change of main catheters were assessed. Information about the use about sheathless approach and catheters were obtained from the material registration system. All catheters were braided.

Results 503 sheathless interventions with 4 F catheters from the groin were documented. The spectrum comprised bleeding embolization, diagnostic angiographies, arterial DOTA-TATE-therapy, uterine fibroid embolization, transarterial chemotherapy, transarterial radioembolization and others. In 31 cases (6 %) a change of the main catheter was required. In 381 cases (76 %) a microcatheter was utilized. No clinically relevant adverse events were observed (grade 2 or higher [CIRSE AE-classification]). None of the cases later required conversion to a sheath-based intervention.

Conclusions Sheathless interventions with a 4 F braided catheter from the groin are safe and feasible. It allows for a broad spectrum of interventions in daily practice.

Keywords Sheathless, Vascular access, Femoral, Transarterial, Braided catheter, 4 F

Background

The main location of adverse events in transarterial interventions is the vascular access (Azzalini et al., 2015; Moran et al., 2001). The complication rate is related to the diameter of the introduced catheter or sheath (Doyle et al., 2008; Kern et al., 1990; Marso et al., 2010; Minici

et al., 2020; Moran et al., 2001; Stone & Campbell, 2012). As a result, many interventional centres attempt to use the smallest vascular access that allows for safe conduction of the planned intervention. Several studies have shown reduced complication rates, safety, and feasibility of sheathless interventions at other locations or with small study populations (Mamas et al., 2017; Oguro et al., 2016; Ruzsa et al., 2016). Therefore, this study aimed to evaluate the safety and feasibility of sheathless interventions with braided 4 F catheters from the groin in daily practice.

*Correspondence:

Jonathan Nadjiri
jonathan.nadjiri@tum.de
Department of Interventional Radiology, School of medicine, Klinikum rechts der Isar, Technical University of Munich, Ismaninger Straße 22, 81675 Munich, DE, Germany



© The Author(s) 2023. **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit <http://creativecommons.org/licenses/by/4.0/>.

Methods

Acquisition of data

Standard procedures that are not expected to require a change of the mother catheter are usually performed without a sheath. For this study we included all sheathless interventions between May 2018 und September 2021. The information about catheters, intervention characteristics and adverse events were obtained from the hospital information system and the radiology information system.

Study population and parameters of interest

503 interventions were documented. Parameters of interest were the type of intervention, gender, patient’s age, type of used catheters, use of microcatheters and adverse events. Adverse events were classified according to the CIRSE classification system of adverse events (Filippiadis et al., 2017). Grade 1 events (complication during the procedure which could be solved within the same session; no additional therapy, no post-procedure sequelae, no deviation from the normal post-therapeutic course) were not documented and therefore were not available for analysis. For the choice of the appropriate catheter previous CT scans of the patients were carefully reviewed. CT was not used for evaluation of the access but only for the intervention target.

Catheters

All selective catheters were braided 4 F Tempo® catheters (Cordis®, Cardinal Health, Inc.®, USA). All used micro catheters were 2.7 F Terumo® (Japan) Progreat® catheter sets with the wire included.

Description of access

All interventions were conducted without any sedation or analgesia besides local anaesthesia with 5ml scandicain (2%). Arterial puncture was done without image guidance by default. If that approach was unsuccessful fluoroscopy was used or sonographic guidance. Vascular access was gained using a Seldinger needle Cook® (USA) utilizing the double wall technique. For all interventions a 0.035” hydrophilic guide wire was used for vascular access. Neither an incision was made nor were dilators used. Then the main catheter was inserted via the above-mentioned guidewire. In case of a required change of the main catheter, the guidewire was advanced and left in place and the catheter was exchanged analogous to a sheath-based intervention. After the intervention the puncture site was compressed manually for 2-10 min. By default, a pressure

bandage for 24h was applied and strict bed rest for 4 hours was recommended.

Statistics

R Statistics (R version 3.5.3 (2019-03-11) -- "Great Truth") was used for descriptive statistics (Team RC, 2019).

Results

Study population

In total, 503 sheathless interventions via an arterial femoral access were analysed. The mean age was 64.8 (± 15.3) and 60% were male; further details are provided in Table 1.

Interventions

The indications for interventions are provided in Table 1 and the listing of catheters used is provided in Table 2. Three hundred eighty-one interventions required superselective microcatheters for diagnostic purposes, for embolization including chemoembolization, radioembolization or coiling. In 31 cases (6%), at least one change of the main catheter was necessary due to anatomic circumstances or for interventions/diagnostics of different areas, e.g., lower extremities first and upper

Table 1 Patients characteristics

| | |
|---|---------------|
| Male | 300 (60%) |
| Age | 64.8 (± 15.3) |
| Indication for angiography | |
| Bleeding | 81 (16%) |
| Diagnostic angiography | 145 (29%) |
| Abdomen | 109 (22%) |
| Lower extremities | 21 (4%) |
| Upper extremities | 15 (3%) |
| Arterial 177-Lu-DOTA-TATE therapy | 53 (11%) |
| Uterus fibroma embolization | 41 (8%) |
| Trans-arterial radioembolization | 84 (17%) |
| Trans-arterial chemotherapy | 86 (17%) |
| Other (e.g. tumor embolization or splenic embolization) | 13 (3%) |

Table 2 Catheter characteristics

| | |
|---|-----------|
| C2-configuration | 291 (58%) |
| RDC1-configuration | 102 (20%) |
| H1- configuration | 18 (4%) |
| Pig-Tail-configuration | 3 (< 1%) |
| S1-configuration | 88 (17%) |
| Other | 1 (< 1%) |
| Use of microcatheter | 381 (76%) |
| Intervention required change of the main selective catheter | 31 (6%) |

extremities second in the same session. During the procedures, the interventionalists noticed improved rotation longitudinal and rotational positioning stability due to the higher friction of the catheter against the surrounding tissue e.g. compared to the low friction of a catheter in a teflon sheath.

Adverse events and complications

Peri-interventionally, no issues or complications related to the vascular access occurred. Adverse events were not documented in patients' medical documents. However, grade 1 adverse events were not specifically evaluated and documented in clinical practice, respectively. No intervention had to be aborted as a consequence of a sheathless approach. No conversion to a sheath-based intervention was required.

Discussion

The main findings of this study are highly indicative that sheathless access via the groin using braided 4 F catheters is safe and feasible in daily practice for common transarterial interventions.

Practical aspects

Size of vascular access devices have been proven to be an important factor for patient safety in endovascular medicine (Uhlemann et al., 2012). Although in clinical practice interventionalists attempt to reduce the size of vascular access devices, some studies were not able to detect an effect for smaller sheaths like 4 F vs. 6 F as a cause of major complications; the study did show significantly increased minor complications for 6 F interventions (Chung et al., 2018). The seemingly low number of required catheter changes is a result of two reasons. First, the here described technique has been the standard for one of the authors for a long time. He supervised the included study interventions and advised regarding the catheter choice. Secondly, our study population included a large proportion of liver interventions like trans-arterial chemoembolization or radioembolization. As a consequence, several patients underwent repetitive angiographies. Therefore, the appropriate catheter can be chosen after reviewing the previous angiographies.

Advantages

There are several reasons for this approach. Bleeding patients often suffer from impaired coagulation; in those situations, a small puncture lesion seems to be especially worthwhile. Further, the authors have the impression that the required compression time is significantly lower compared to a 4 F sheath which practically has a 6 F outer diameter. Unfortunately, there are no documented compression times available for our study population nor for

a comparable matching collective. Therefore, this has to be evaluated in further studies.

The authors did not experience an increased pain perception of the patients compared to sheath-based interventions. Compared to a sheath-based intervention a sheathless approach leads to a better longitudinal and rotational positioning stability of the catheter due to the friction of the catheter with the surrounding tissue. This can be particularly helpful for catheterizing intercostal vessels from top to bottom in search for a bleeding. This characteristic is also very helpful for intraarterial DOTA-TATE treatments. In this situation the catheters remain stable so that patients can be administered the medication in the target artery with relatively high reliability. We also experienced a higher willingness of colleges with limited interventional education to remove just a catheter in comparison to removing a sheath. Furthermore, the positioning stability allows for a self-maintaining rotational preload on a selective catheters which occasionally is required to steer catheter stiffness with torque. Without incisions the vascular access point is practically invisible after 7 days further underlining the minimal invasive character of interventional radiology; this is a subjective observation and was not part of the primary study analysis. However, a certain proportion of the study population underwent repetitive arterial interventions such as trans-arterial radioembolization and the planning angiography shortly before that. The intervals of these interventions usually range from a few days up to two weeks. Trans-arterial chemoembolization often is performed repetitively but with longer intervals. However, after sheathless intervention the previous puncture site could not be determined after approximately seven days and therefore not be used as orientation for the following interventions. Sheathless interventions can reduce material costs. If a facility only or mainly uses braided catheters, sheathless intervention spares a sheath for every intervention. In most cases the cost of the sheath is half the price of the catheter. In general, selective braided catheters are not significantly more expensive compared to the few non-braided selective catheters on the market. Therefore, sheathless intervention is likely to reduce the material costs even if a facility has to switch from non-braided to braided catheters for the technique.

Disadvantages

The main disadvantage remains the slightly different feeling compared to sheath-based interventions; this can be difficult for beginners. The above-mentioned increased positioning stability can be perceived negatively by some interventional radiologists. Especially in hands of less experienced interventionalists there is risk of a subcutaneous malrotation of the catheter and subsequent tear

off in the worst case. Insertion of the catheter via a guide wire without a sheath and without an incision is associated with high resistance; especially the skin and the arterial wall cause punctually high resistance. However, after insertion of the tip of the catheter into the arteria the resistance is neglectable. Additionally, a used and warmed catheter might not be stiff enough to penetrate skin and the arterial wall via a guide wire.

It is to assume that repeated change of the main catheter without a sheath causes increased trauma to the arterial wall. Therefore, in the authors' daily practice sheath-less angiography is only attempted after careful evaluation of previous angiographies or CT-scans. Only in case of a very high likelihood that successful intervention is possible with just one catheter, a sheathless approach was attempted. However, in 6 % of the cases in this study at least one exchange of the main catheter was performed without a sheath. Even in these cases no relevant adverse events occurred indicating that exchange of catheters without a sheath might be safe.

Sheathless access was not attempted with non-braided catheters; it is to assume that it might be more difficult if not impossible but has to be supported by data.

Limitations

This is a single centre study. Adverse events of the category 1 were not documented; even though occurrence of category 1 adverse events is clinically irrelevant this study could not evaluate the incidence of category 1 events with 4 F sheathless interventions from the groin. This study did not compare the sheathless approach against sheath-based interventions in a randomized study nor were compression times documented that could be compared. No relevant adverse events were observed in the entire study, therefore the precise complication rate cannot be calculated. The number of atherosclerotic patients was not determined.

Conclusion

Sheathless vascular access with braided 4 F catheters is safe and feasible for common body interventions in daily practice. Sheathless interventions might especially be interesting for facilities performing a large number of transarterial chemoembolization and/or radioembolization including angiographies for radioembolization planning.

Acknowledgements

We are indebted to the medical and technical staff members of our interventional laboratories for their invaluable contribution. We especially thank Stephan Forster, Melanie Fritz, Christoph Knappe, Melissa Mayr, Neriban Ramadani and Katharina Scherer for their effort, patience and constant support.

Authors' contributions

JN, TW and PP analysed and interpreted the patient data. TW developed the technique. MM, TG and JN developed the study design. JN drafted the manuscript. All revised the draft of the manuscript and read and approved the final manuscript.

Funding

Open Access funding enabled and organized by Projekt DEAL. This study was not funded; there is no involvement from outside the department.

Availability of data and materials

The data file is available on reasonable request from the corresponding author.

Declarations

Ethics approval and consent to participate

This study is approved by the local ethics committee (Ethikkommission der Fakultät für Medizin der Technischen Universität München, 2022-258-S-KH). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This is a retrospective study of a in-house standard technique; consent for participation was waived by the local ethics committee.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Received: 18 December 2022 Accepted: 23 January 2023

Published online: 16 February 2023

References

- Azzalini L, Tosin K, Chabot-Blanchet M et al (2015) The benefits conferred by radial access for cardiac catheterization are offset by a paradoxical increase in the rate of vascular access site complications with femoral access: the Campeau radial paradox. *JACC Cardiovasc Intervent* 8(14):1854–1864
- Chung R, Weller A, Morgan R, Belli A-M, Ratnam L (2018) Are complication rates lower with 4-Fr versus 6-Fr transfemoral arterial access—prospective audit at a single interventional radiology centre. *CVIR Endovasc* 1(1):1–7
- Doyle BJ, Ting HH, Bell MR et al (2008) Major femoral bleeding complications after percutaneous coronary intervention: incidence, predictors, and impact on long-term survival among 17,901 patients treated at the Mayo Clinic from 1994 to 2005. *JACC Cardiovasc Intervent* 1(2):202–209
- Filippiadis D, Binkert C, Pellerin O, Hoffmann R, Krajina A, Pereira P (2017) Cirse quality assurance document and standards for classification of complications: the cirse classification system. *Cardiovasc Intervent Radiol* 40(8):1141–1146
- Kern MJ, Cohen M, Talley JD et al (1990) Early ambulation after 5 French diagnostic cardiac catheterization: results of a multicenter trial. *J Am College Cardiol* 15(7):1475–1483
- Mamas MA, George S, Ratib K et al (2017) 5-Fr sheathless transradial cardiac catheterization using conventional catheters and balloon assisted tracking: a new approach to downsizing. *Cardiovasc Revasc Med* 18(1):28–32
- Marso SP, Amin AP, House JA et al (2010) Association between use of bleeding avoidance strategies and risk of periprocedural bleeding among patients undergoing percutaneous coronary intervention. *Jama* 303(21):2156–2164
- Minici R, Paone S, Talarico M et al (2020) Percutaneous treatment of vascular access-site complications: a ten years' experience in two centres. *CVIR Endovasc* 3:1–10

- Moran CJ, Milburn JM, Cross DT III, Derdeyn CP, Dobbie TK, Littenberg B (2001) Randomized controlled trial of sheaths in diagnostic neuroangiography. *Radiology* 218(1):183–187
- Oguro S, Nakatsuka S, Inoue M, Yashiro H, Tamura M, Jinzaki M (2016) Feasibility of a Sheathless Arterial Access Using a 4-F catheter and a triaxial system for transcatheter arterial chemoembolization for hepatocellular carcinoma. *Intervent Radiol* 1(2):39–44
- Ruzsa Z, Tóth K, Nemes B et al (2016) Transradial and transulnar access for iliac artery interventions using sheathless guiding systems: a feasibility study. *Catheter Cardiovasc Intervent* 88(6):923–931
- Stone PA, Campbell JE (2012) Complications related to femoral artery access for transcatheter procedures. *Vasc Endovasc Surg* 46(8):617–623
- Team RC (2019) R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing
- Uhlemann M, Möbius-Winkler S, Mende M et al (2012) The Leipzig prospective vascular ultrasound registry in radial artery catheterization: impact of sheath size on vascular complications. *JACC Cardiovasc Intervent* 5(1):36–43

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Submit your manuscript to a SpringerOpen[®] journal and benefit from:

- ▶ Convenient online submission
- ▶ Rigorous peer review
- ▶ Open access: articles freely available online
- ▶ High visibility within the field
- ▶ Retaining the copyright to your article

Submit your next manuscript at ▶ [springeropen.com](https://www.springeropen.com)
