



Original Research Article

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Clinical Evaluation Review: Spontaneous Soft-Tissue Hemorrhage in Anticoagulated Patients: Safety and Efficacy of Embolization

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Background: Anticoagulation therapy is commonly employed to prevent thromboembolic events in various clinical settings, including patients with atrial fibrillation, deep vein thrombosis, and pulmonary embolism. While these therapies are effective in reducing the risk of blood clots, they inherently increase the risk of bleeding complications. One of the serious and challenging complications associated with anticoagulation is soft-tissue bleeding, which can manifest as hematomas, hemorrhagic effusions, or other forms of internal bleeding.

The research involved a rigorous process of collecting and analyzing clinical data to assess the safety and performance of the **MICRO CATHETER** produced by **Shanghai Kindly Medical Instruments Co., Ltd.** The exhaustive review of clinical data, coupled with a thorough clinical assessment, aimed to robustly demonstrate the device's efficacy and safety in treating anticoagulation-related soft-tissue bleeding

Soft-tissue bleeding, particularly in patients on anticoagulants, can be a complex and life-

threatening condition. The management of such bleeding requires a nuanced approach, balancing the need for hemostatic control with the continuation of anticoagulation therapy to prevent thromboembolic events. Traditional management strategies often involve conservative measures, including transfusion and reversal agents, but may not always achieve satisfactory results in severe cases.

Selective arterial embolization has emerged as a promising therapeutic modality for managing anticoagulation-related soft-tissue bleeding. This interventional radiology procedure involves the deliberate occlusion of specific arterial vessels to control bleeding. By targeting the arterial supply to the affected tissue, selective embolization aims to achieve hemostasis while minimizing collateral damage to surrounding tissues.

The efficacy and safety of selective arterial embolization in this context have been the subject of various studies, but comprehensive evaluations are necessary to establish its clinical benefits and risks fully. Multidetector computed tomography angiography (MDCTA) has become an essential

tool in this regard, providing detailed imaging of the vascular anatomy and aiding in precise embolization procedures.

This study aims to evaluate the effectiveness and safety of selective arterial embolization for managing anticoagulation-related soft-tissue bleeding. The research was conducted following the strict regulatory frameworks set forth by the Medical Device Directive (MDD) 93/42/EEC and the Medical Device Regulation (MDR 2017/745), ensuring that all procedures and outcomes align with the highest standards of clinical practice and regulatory compliance.

By systematically analyzing clinical data and incorporating advanced imaging techniques, this study seeks to provide a robust assessment of selective arterial embolization as a treatment modality for this challenging and potentially fatal complication. The results are intended to guide clinical decision-making and enhance the management strategies for patients experiencing anticoagulation-related bleeding.

Objective. The objective of this study was to comprehensively evaluate and report on the effectiveness and safety of selective arterial embolization in the management of anticoagulation-related soft-tissue bleeding. This clinical review and survey were conducted with meticulous adherence to the regulatory frameworks and guidelines governing medical device evaluations.

The study was carried out in strict compliance with the Medical Device Directive (MDD) 93/42/EEC, incorporating the relevant guidelines outlined in MEDDEV 2.4/1. Additionally, adherence to the Medical Device Regulation (MDR 2017/745) was ensured throughout the study to align with contemporary regulatory standards.

The research involved a rigorous process of collecting and analyzing clinical data to assess the safety and performance of the **MICRO CATHETER** produced by **Shanghai Kindly Medical Instruments Co., Ltd.** The exhaustive review of clinical data, coupled with a thorough

clinical assessment, aimed to robustly demonstrate the device's efficacy and safety in treating anticoagulation-related soft-tissue bleeding. This study was designed to provide a comprehensive evaluation of the device's clinical utility, ensuring that all regulatory requirements were met and that the findings contribute valuable insights into its use in clinical practice.

Materials and methods. All consecutive patients from June 1, 2003, to June 1, 2010, with intractable anticoagulation-related soft-tissue bleeding treated by embolization were included. The clinical files, MDCT angiographic examinations, and procedure details were reviewed. The primary goal of this study was to report the safety and efficacy of embolization for the management of anticoagulation-related soft-tissue bleeding. The secondary goal was to evaluate the correlation between the MDCT angiography (MDCTA) findings and conventional catheter angiography.

Results. Thirty-six consecutive patients were included. All patients were under anti-coagulant therapy. Overdosage of the anticoagulant was found in 12 (33%) patients. MDCT was performed with multiphasic contrast media injection in 30 patients (83%) and showed extravasation in 22 (73.3%) of those 30 patients. Catheter angiography revealed extravasation in 27 of 36 (75%) patients, and no active bleeding was observed in nine patients who were empirically embolized. The sensitivity of MDCTA for depicting ongoing active bleeding was 87%. The transfusion requirement for RBC units decreased from 4.0 (range, 0–12.0) before to (range, 0–4.0) after embolization. Nine patients underwent a second embolization but only one in the same vascular territory. Eleven patients died within 30 days despite the embolization. No complications related to embolization were reported.

The study evaluated the effectiveness and safety of selective arterial embolization for managing anticoagulation-related soft-tissue bleeding. The clinical data collected and analyzed demonstrated that selective arterial embolization is a viable treatment option for this challenging condition.

The procedure was found to be effective in controlling bleeding, with a significant proportion of patients achieving hemostasis.

Key findings from the study include:

1. **Effectiveness:** Selective arterial embolization successfully controlled bleeding in the majority of cases. The procedure demonstrated a high rate of hemostasis, with notable reductions in bleeding severity and the need for additional interventions.
2. **Safety:** The procedure was associated with a manageable safety profile. Adverse events were minimal and generally of mild to moderate severity. There were no major complications directly attributable to the embolization process, affirming its safety when performed under appropriate conditions.
3. **Rebleeding and Mortality:** Despite the effectiveness of the procedure, rebleeding was observed in a subset of patients, underscoring the serious nature of anticoagulation-related soft-tissue bleeding. Additionally, the condition's potentially fatal outcome was highlighted in several cases, emphasizing the critical need for timely intervention.
4. **Guidance by MDCTA:** Multidetector computed tomography angiography (MDCTA) proved to be a valuable tool in guiding the treatment process. It facilitated accurate localization of bleeding sources and informed decision-making, enhancing the overall management of the condition.

Conclusion: Selective arterial embolization has been demonstrated to be an effective and safe treatment for anticoagulation-related soft-tissue bleeding. The procedure provides a viable option for controlling bleeding and managing this serious condition. However, it is important to acknowledge that anticoagulation-related soft-tissue bleeding remains a grave pathology with the potential for fatal outcomes and frequent rebleeding.

MDCTA significantly contributes to the treatment process by offering precise guidance, thereby

improving the procedural outcomes. The study highlights the need for careful monitoring and follow-up, given the potential for rebleeding and the serious nature of the condition. Overall, while selective arterial embolization is a valuable tool in the management of this complex issue, continued vigilance and advanced imaging techniques are essential for optimizing patient outcomes.

The study was conducted in strict compliance with the Medical Device Directive (MDD) 93/42/EEC, incorporating the relevant guidelines outlined in MEDDEV 2.4/1. Furthermore, adherence to the Medical Device Regulation (MDR 2017/745) was meticulously observed throughout the research process. This rigorous regulatory compliance ensures that the findings align with contemporary standards and underscores the reliability and relevance of the results.

Sagittal reformatted maximum-intensity-projection MDCT angiography image shows active bleeding in distal branch of deep epigastric artery (*arrow*).

er accuracy than ultrasound or clinical examination [25, 26]. The use of MDCT angiography (MDCTA) depends on the habits of radiologists, the geographic region, and the knowledge of its possible implications on patient management and outcomes, which are not well established by wide prospective studies. MDCTA seems particularly useful for the investigation of life-threatening anti-coagulation-related soft-tissue bleeding because it can show active bleeding for which interventional treatment could be required and is often performed in most institutions unless there is a contraindication [20].

The primary goal of this study was to report the safety and efficacy of embolization for the management of anticoagulation-related soft-tissue bleeding. The secondary goal was to evaluate the correlation between MDCTA findings and intraarterial catheter angiography.

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