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Implementing a minimally invasive approach (combining radial approach, small guiding catheters and minimization of double access) for coronary chronic total occlusion intervention according to the hybrid algorithm: The Minimalistic Hybrid Algorithm

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ABSTRACT

Percutaneous recanalization of coronary chronic total occlusions (CTOs) traditionally relies on the use of dual access and large bore catheters, with trans-femoral approach adoption in most of the cases. Aim of this manuscript is to describe an alternative algorithm, that we called "Minimalistic Hybrid Algorithm", in order to minimize the use of double access, large bore catheters, and femoral approach thus reducing patient's discomfort and possibly procedural complications. This algorithm can be interpreted as an evolution of the classic "Hybrid Algorithm" and requires the operator to be confident with all techniques known in this conventional algorithm. Indeed, all possible techniques and approaches of the conventional hybrid approach to treat CTOs are included in a novel diagram for procedural strategy, which offers an alternative sequence of steps to limit, whenever possible, the invasiveness of the procedure. After dividing the cases in "simple" or "complex" CTO lesions according to the available complexity scores and to the "feeling", knowledge and expertise of the operator, a systematic description of the procedural steps is provided. This includes antegrade and retrograde approaches, as well as subintimal and intra-luminal techniques, in order to maintain the simpler single-catheter transradial strategies in the first line for the simple CTO, and the adoption of more complex, double access and transfemoral ones in the further steps. The minimalistic hybrid algorithm herein described is a possible alternative sequence of steps in the setting of CTO recanalization, with the potential of limiting the use of double access, large bore catheters, and femoral approach.

1. Introduction

Percutaneous coronary intervention (PCI) for revascularization of chronic total occlusions (CTO) has experienced increasing interest and dedication in the last decade. Major steps forwards have been developed across these years, as the recently introduced and validated Hybrid Algorithm. By means of this novel approach, operators facing CTO PCI handle a wide range of different techniques and approaches, with the purpose of limiting procedural time, contrast dye administration and materials consumption, with additional optimization of the procedural success [1].

Until now, revascularization of CTO has traditionally relied on the femoral approach via large sheaths and catheters, as a guarantee of achieving maximal support for materials penetration and advancement into the CTO lesion. Indeed, the use of 8F guiding catheters, associated with long supportive femoral sheaths has the promise of offering higher back-up forces and a broadly more stable system. However, the extensive use of femoral approaches in coronary interventions has already been demonstrated to increase incidence of adverse events, including all-cause mortality, major adverse cardiac events (MACE), bleedings and major vascular complications. Of note, this phenomenon has been described not only in the setting of acute coronary syndromes, where the incidence of these events has already been reported higher than in radial procedures, but even more pronounced in those of stable coronary artery disease PCI [2].

Of interest, a recent sub-analysis of the RECHARGE registry investigating the procedural outcomes of CTO PCI performed by a fully-transradial (fTRA) approach has reported comparable success rates as compared with transfemoral procedures, including subgroups of patients with higher lesion complexity (J-CTO score ≥ 3) [3]. Furthermore, when fTRA was used, the total amount of contrast dye administered resulted lower than in the transfemoral access population.

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These promising results, despite being derived from a single large registry, are in contrast with those derived from reports of less recent cohorts [4], which may suggest that evolutions in materials, techniques, methodology and operator expertise may nowadays significantly facilitate the procedural steps in this very complex setting of PCI.

Aim of this manuscript is to describe an alternative, "evolved" version of the hybrid algorithm, called "Minimalistic Hybrid Algorithm", which has the purpose of reducing patients' risks and discomfort by limiting, when possible, the adoption of femoral approach, use of large bore catheters and use of double access, however still allowing all techniques contemplated in the conventional hybrid algorithm.

2. Rationale of the "Minimalistic Hybrid Approach"

The primary goal of any algorithm in CTO revascularization is that of obtaining the highest procedural success rate, which should be balanced with acceptable safety profile and reasonable resources consumption. In the hybrid algorithm, this is achieved by adopting a revascularization strategy that maintains available all four possible options for crossing the CTO lesions, namely antegrade wire escalation (AWE), antegrade dissection re-entry (ADR), retrograde wire escalation (RWE) and retrograde dissection re-entry. These different approaches are then consecutively attempted until successful CTO crossing, with an order that reflects the operator's preferences and the likelihood of success based on baseline angiography. In the "Minimalistic Hybrid Algorithm" all the four options are also kept into consideration, but the order in which they are attempted is focused on the priority of performing the procedure minimizing double access, large bore catheters, and femoral approach.

In the settings of techniques with highest level of complexity (including ADR with CrossBoss-Stingray), however, the authors believe that a complete exclusion of the trans-femoral approach is, beside theoretically possible, not fully justified. In fact, there are still specific advanced CTO PCI techniques that require an 8F guiding catheter (e.g. proximal cap puncture with real-time IVUS-guidance), which is commonly utilized through a trans-femoral access.

For this reason, a possible flowchart including all conventional CTO revascularization techniques will be presented, leaving those mandating large sheath's support as the last alternative.

3. Description of the algorithm

A diagram showing the complete "Minimalistic Hybrid Algorithm" is available in Fig. 1.

As a first step, the CTO lesion is accurately assessed at basal angiography, with specific focus on presence of proximal cap ambiguity, presence of possible microchannels within the body of the CTO, presence of competitive flow in the distal segment after the CTO to assess the presence of different collateral circulations and all features included in the scores for CTO complexity [5,6]. Good contralateral injections is also mandatory in this step and if not present in the baseline angiogram performed before the CTO attempt, it can be done in the same session of the CTO just before starting the CTO procedure. This basal evaluation is crucial for dividing every case in a "Simple" or "Complex" CTO scenario.

3.1. "Simple" CTO scenario

This is generally defined by the presence of a clear proximal cap and/or presence of microchannel in the body of the CTO lesion itself, associated with a lower CTO complexity score (in the majority of the cases: J-CTO ≤ 1 and Progress ≤ 1). However, this scenario reflects those CTO where the operator feels "a priori" confident in crossing the occlusion with relative ease, besides the classifications scores. This subgroup of lesions is safely and successfully treated with AWE in most of the patients. Definitely, a broad expertise of the operator is required to judge properly this type of CTO. If, during the procedure, the operator encounters unexpected difficulties, a rapid switch to the "Difficult CTO scenario" algorithm is always feasible and prompt.

A first approach is made through a single 6F catheter procedure via transradial access without contralateral injection, and attempts of CTO lesion crossing by means of soft wires (e.g. Fielder XT-A or Fielder

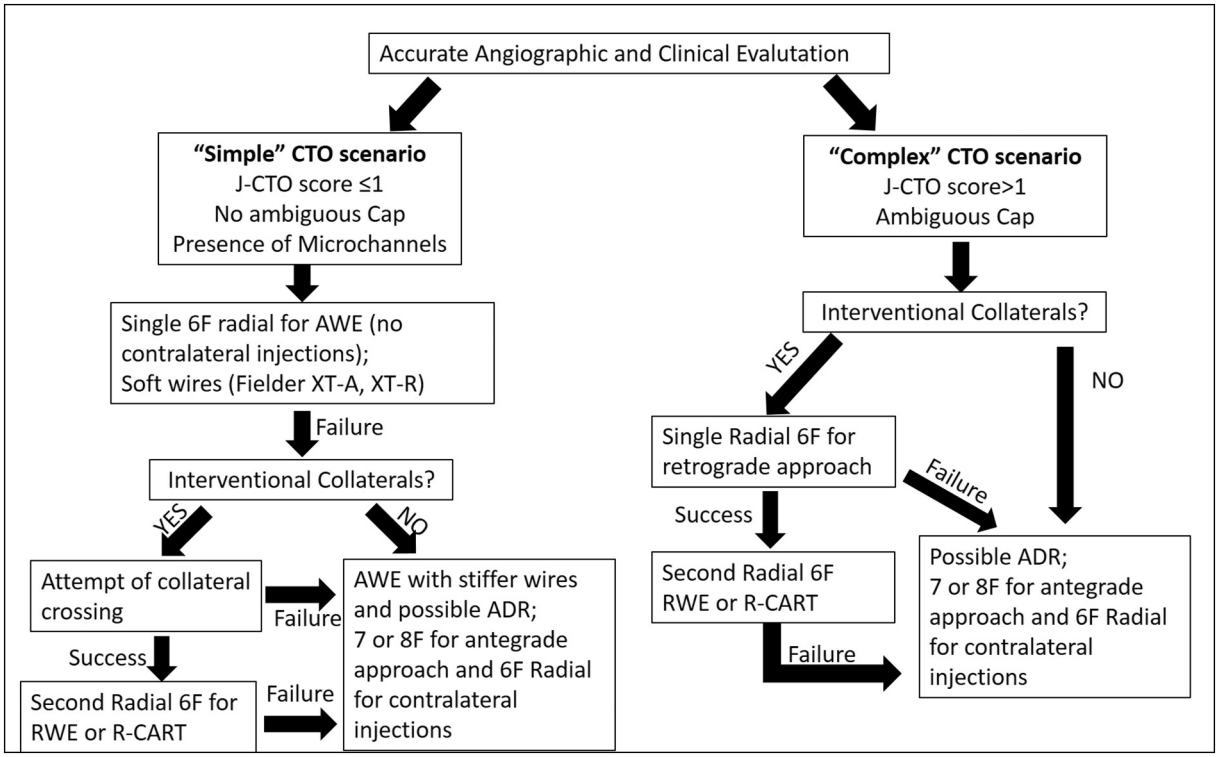

Fig. 1. Diagram showing the "Minimalistic Hybrid Algorithm".

XT-R) with support of a microcatheter, avoiding, if possible, sub-intimal space penetration. In case of failure, the operator should evaluate the presence of interventional collaterals and the likelihood of success of a possible retrograde approach, if compared with further antegrade attempts with step up to stiffer wires (this evaluation has been done already before the beginning of the antegrade attempt, by means of proper inspection of the angiogram done before the current procedure or by acquisition of additional angiograms of the donor vessel in the same session of the CTO before starting the attempt). If the retrograde approach is judged more feasible and with a higher chance of success, than the same radial access could be converted to a retrograde access and adopted to attempt retrograde collateral crossing. If successful collateral crossing is achieved by reaching the distal cap of the CTO lesion through the collaterals, a second 6F transradial access can be positioned and adopted for the antegrade approach to the CTO lesion, which will then be recanalized by means of RWE or reverse controlled antegrade-retrograde subintimal tracking (R-CART).

If the retrograde approach is judged less feasible or in case of failure in collateral crossing, advanced antegrade approaches represent the remaining available strategies (including ADR). For this reason, a larger catheter should be adopted for maintaining available the ADR technique by means of CrossBoss-Stingray, thus a 7F (or 8F) transradial or transfemoral access should be placed, and the already present transradial access used for the contralateral injection. The procedure can then be finalized with either an AWE with stiffer guidewires (e.g. Gaia) or contralateral injection to control proper pathway of the wire or with ADR technique.

3.2. "Complex" CTO scenario

Lesions not fulfilling the criteria for the previous group are included here. These CTOs generally present with ambiguous cap and other adverse features generating higher complexity scores (generally, J-CTO > 1 and PROGRESS > 1). Also in these cases, a key role is played by the presence (or absence) of interventional collaterals, which allow (or prevent) applicability of retrograde approaches. Indeed, the first step in cases with good collateral channels for retrograde techniques is represented by 6F transradial access and cannulation of the donor vessel, with the purpose of attempting retrograde collateral crossing thus reaching the distal cap of the CTO lesion. If successful passage of the collaterals, the next step would consist of antegrade approaching the CTO lesion with another 6F transradial access and conclude the CTO recanalization by means of RWE or R-CART techniques. In case of absent interventional collaterals or failed retrograde channels crossing, the possible use of ADR should be taken into account, thus a 7F (or 8F) transradial or transfemoral sheath inserted, maintaining the first 6F trans-radial access for contralateral injections (including a step-up to 8F of one trans-radial access when vascular size and patient's constitution allow for it). Following these steps, all possible antegrade and retrograde techniques can be attempted to cross the complex CTO lesions.

As an additional general suggestion, when radial access is not available or not obtained (for example in case of failure to puncture the radial artery or in case of spasm), an ulnar approach can also be considered in order to achieve a "wrist-approach", without resorting to trans-femoral access [7].

4. Discussion

In this manuscript, we have described a novel advanced algorithm with the potential of highly reducing the use of large bore transfemoral access in CTO-PCI. At present, the use of transfemoral access in this setting is still considered the "way to go" for maximized procedural success rates. However, a fully-transradial approach in CTO revascularization has proven feasible and comparably successful in a recent report by our group [3]. This is confirmed, at least, in majority of lesion complexity settings (as expressed by J-CTO score). On the other hand, the use of transfemoral approach cannot be fully excluded from the armamentarium of CTO operators, especially considering that some advanced techniques (e.g. ADR with CrossBoss-Stingray and "stick and swap" technique, with additional balloon, catheter-extension or IVUS-guided re-entry) specifically demand for higher catheter diameters. Of note, in some cases the need for large catheters (7F or even up to 8F) is also fulfilled through trans-radial access when patient's constitution allows for it, which would result even more preferable over trans-femoral puncture when the patient has already received procedural anticoagulation.

For these reasons, the algorithm herein described has the purpose of increasing a "minimalistic" vascular access for CTO procedures by encouraging the use of radial or ulnar approaches in most of the cases but also acknowledging the use of femoral access when necessary. In addition, ongoing developments such as miniturization of endovascular devices (for example Stingray Low Profile for ADR, TrapLiner device [already available in the US, soon also in Europe]) and the use of sheathless techniques can limit the amount of cases requiring large-bore arterial sheaths or femoral approach in a consistent number of patients [8]. In addition, the use of dedicated devices such as the Glidesheath Slender (GSS, Terumo, Tokyo, Japan) can facilitate the adoption of TRA with 7-F guiding catheters, minimizing the outer diameter of otherwise large bore sheaths. Potential advantages of a widespread adoption of this strategy would consist in reduced rates of adverse clinical events, including all-cause death, MACEs and major bleedings [2], associated also with a reduced discomfort of the patient after the procedure. Furthermore, the adoption of a single catheter only and the use of smaller catheters through the radial approach is associated with less contrast dye administration [3], with a possible minor impact on kidney function. Moreover, the use of smaller catheters also may reduce the risk of intra-catheter thrombosis (as less hardware can be passed through smaller catheters at the same time), another potentially dreadful complication of CTO PCI if proper anticoagulation is not achieved and maintained.

In order to overcome the lack of support offered by the trans-wrist access, some expedients should be adopted. First of all, the use of microcatheters is always mandatory, for both antegrade and retrograde approaches, when performing CTO PCI. In addition, the use of catheter-extensions (such as Guideliner or Guidezilla) can provide the needed back-up force for cap penetration, collaterals crossing and catheter stability. Another trick is represented by the guiding catheter choice, which should favour slightly oversized "aggressive" curves when working in the left coronary system (e.g. Extra-BackUp 4 or 4.5 instead of 3.5). Similarly, the use of more supportive guiding catheters should be the first line of choice when working in the right coronary artery (e.g. Amplatz left instead of Judkins right catheter). Furthermore, despite transradial access is normally characterised by lower diameter catheters, the possibility of performing the anchoring-balloon technique is a concrete option for 6F guiding in the majority of the cases.

5. Limitations

The strategy we have described here has the advantage of offering a possible evolution to the conventional Hybrid Approach for CTO recanalization with higher adoption of trans-wrist access thus having the potential to reduce procedural vascular-related complications rate and patients discomfort after the procedure. This algorithm has not the purpose to overcome previously reported algorithms, but is a possible alternative specifically dedicated to expert CTO operators interested in limiting the use of large-bore dual catheter trans-femoral access.

However, this algorithm presents also some limitations. First of all, in case of failure of advanced techniques after double-radial access achievement, the operator is forced to obtain a third vascular (femoral) access for more complex techniques (ADR with the CrossBoss-Stingray device or IVUS-guided dissection-reentry), when a step-up to 8F is not possible in one trans-radial access. However, we believe that this is relatively uncommonly necessary, when successful collateral crossing and

distal cap penetration is achieved, especially in the "simple" CTO settings. Secondly, there are some infrequent anatomical and technical conditions where the minimalistic hybrid approach cannot be applied in details, such as ipsilateral retrograde techniques [9,10], CTOs involving grafts that demand selective injection for collaterals filling and other peculiar settings (e.g. subclavian stenosis, arterial-venous fistula…). In these settings, resorting to larger bore catheters and transfemoral approach may be indicated as a first-line option. Third, gaining a second vascular access after the beginning of the procedure may (in some cases) require a femoral puncture with an augmented activated clotting time (ACT>300 s). Despite not demonstrated yet, this may theoretically expose the specific patient to a higher risk of bleedings and vascular complications.

Finally, the application and feasibility of this minimalistic hybrid approach, besides commonly followed in our centre with satisfactory results, has still to be demonstrated in clinical practice.

6. Conclusions

We propose an alternative "minimalistic" hybrid approach for CTO-PCIs, with the aim of reducing large bore catheters and double access adoption. According to the available data, the advantages of a widespread reduction of transfemoral access also in this complex setting of PCI, could be translated into a significant decrease of procedural-related complication and adverse clinical events.

Conflict of interest

The authors have no conflict of interest to declare.

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