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IM - COMMENTARY

Telemedicine and decentralized models of care: from anticoagulant monitoring to an expanded concept of vascular medicine

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Oral anticoagulation is the mainstay therapy for primary and secondary prevention of thromboembolic events in patients with venous thromboembolism (VTE) and atrial fibrillation. After the introduction of direct oral anticoagulants (DOAC), the prevalence of anticoagulated patients in the general population progressively increased [1-4]. This trend will likely continue because of novel indications for anticoagulant treatment, e.g., stable atherosclerotic vascular disease [5], and more accurate risk stratification of patients [6, 7].

In light of their efficacy and safety profile, and the ease of use in fixed-dosage regimens, DOAC are overtaking INR-adjusted vitamin-K antagonist (VKA) therapy in several countries [1-4]. However, patients with contraindications to DOAC will still receive VKA. Therefore, the maintenance of structured plans for VKA monitoring remains essential. In this perspective, anticoagulation clinics, which were first created in The Netherlands and Italy primarily for VKA monitoring and dosing, must be reimagined [7, 8].

The ecologic study published in this issue of *Internal and Emergency Medicine* by Tosetto and colleagues [9] is somehow a summary of the Italian experience with anticoagulation clinics interfacing with nursing homes, peripheral hospitals, and general practitioners [10]. At the same time, it may represent a first step towards novel concepts of internal and vascular (tele) medicine. In their study, the authors compare the characteristics of anticoagulant use and outcome of more than 14,000 patients from two Italian provinces [9]. These two cohorts were managed—the main novelty of the study—in the setting of two different care delivery models: (1) a comprehensive management model based on decentralized community health units heavily relying on telemedicine (here referred to as `comprehensive decentralized model') [10] and (2) a `usual care model' pivoting on a single second-level center. These two models were embedded in otherwise similar healthcare settings.

The most striking results are that in the comprehensive decentralized model, as compared with the usual care model: (1) a broader use of anticoagulation (age-standardized prevalence 1.5% vs. 1.0%) was observed, as well as (2) lower annualized rates of thromboembolic complications during VKA therapy (0.36% person-years vs. 0.89% person-years, respectively), particularly among the elderly (0.22% person-years vs. 1.38% person-years) [9]. As indirect as this evidence is, one may cautiously conclude that comprehensive management models improve clinical outcomes by contributing not only to better anticoagulant control in VKA-anticoagulated patients, as previously showed [11], but also to better selection of candidates to anticoagulation. These results are reassuringly in line with those of the prospective, observational, multicenter START Register, which reported major improvements over the last 20 years in the care of VKA-treated patients managed by centers of the Italian Federation of anticoagulation clinics (FCSA) [12].

Statements concerning safety should be made cautiously. The annualized incidence rate of major bleeding in Cremona ('comprehensive decentralized model') was approximately one-third higher than in Vicenza ('usual care model'). This applied to both VKA (0.61% person-years vs. 0.43% person-years) and DOAC (0.26% person-years vs. 0.15% person-years, respectively). However, the uncertainty of these figures is considerable, with largely overlapping confidence intervals of the risk estimates. Not only anticoagulant use, but also differences in demographic characteristics, such as sex distribution [9], and the prevalence of risk factors such as alcohol consumption or smoking between the two cohorts [13], may have influenced the bleeding rates. These factors considerably affect bleeding risk and the quality of

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VKA therapy [14]. Therefore, no firm conclusions can yet be drawn on the potential impact of a management model on safety and net clinical benefit. Still, these findings serve as additional warning that results from different geographical areas are specific to the population that they examined and should always be evaluated against the setting that they refer to.

This study tells us something also on the current practices of DOAC use. First, the use of VKA appears largely predominant in these two Italian provinces, at least compared with other European countries [1-4]. Second, patients who received DOAC had lower rates of thromboembolic and bleeding events. Since it is likely that DOAC had been prescribed to a selected, and possibly healthier population, conclusions on a better risk–benefit profile of DOAC (vs. VKA) should be carefully drawn. However, the results presented by Tosetto and colleagues are consistent with what observed in phase III randomized controlled trials [15], phase IV studies [16], and analyses of nationwide cohort studies providing adjusted estimates [17].

An integrated, comprehensive, decentralized model of care may help to address persisting challenges in the management of anticoagulation and of anticoagulant-related complications. These include, among others, optimization of DOAC compliance, which may be problematic to measure and improve [18], and the establishment of adequate clinical and laboratory follow-up schedule for DOAC-treated patients. Practice-based studies indicate that even a simple but essential laboratory measurement, renal function, is not performed regularly in these patients [19].

Yet, the potential benefits of a comprehensive decentralized vs. usual care system may go well beyond anticoagulant management. It may provide the starting point for an expanded concept of patient care which relies on telemedicine and involves multiple specialisms. The home treatment of acute deep vein thrombosis and pulmonary embolism [20, 21] has proved effective in optimizing the overall use of resources and enhance patients' quality of life and engagement [22-24]. A similar transition has been observed in the field of hemophilia and other chronic bleeding disorders, with increasing interactions between central hubs and multiple specialists at different geographic locations, often achieved via telemedicine and videoconferencing [25]. This made it possible to expand the spectrum of care delivered to patients beyond hemostatic therapy to include, among others, physiotherapy and prevention of orthopedic complications, treatment of viral hepatitis, gynecological consultations, psychological support, and early detection of bleeding events.

As life expectancy increases, multiple comorbidities and chronic therapies become the rule rather than the exception, and management may become too complex to be handled by separate specialist consults. In this perspective, the figure of the specialist in internal and vascular medicine [26] within a comprehensive decentralized care models integrating several specialisms has the potential to manage effectively several other aspects of vascular medicine, including, but not limited to, hypertension, heart failure, and diabetes.

Compliance with ethical standards

Conflicts of interest None reported.

Statements of human and animal rights This article does not contain data derived by any current studies with human participants performed by any of the authors.

Informed consent For this type of study, formal informed consent is not required.

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