EDITORIAL

Health Service Research—Implications for Clinical Practice

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Editorial to accompany the article: „Accuracy in diagnosing deep and pelvic vein thrombosis in primary care—an analysis of 395 cases seen by 58 primary care physicians“ by El Tabei et al. in this issue of *Deutsches Ärzteblatt International*

Acute pulmonary embolism is a common disease, with an annual incidence of 20 cases per 10 000 inhabitants. In the vast majority of patients, the embolism arises from thrombosis of a deep leg vein. Up to 50% of all patients with a deep vein thrombosis (DVT) of the leg have a—frequently clinically silent—pulmonary embolism. The mortality of acute pulmonary embolism is high, at 7% to 11%, and in the majority of cases recurring embolisms are responsible for the fatal event (1). Early anticoagulant treatment of the DVT lessens the risk of embolism and thus greatly improves the prognosis.

The clinical symptoms of DVT may be nonspecific in the extreme. For this reason, the treating physicians frequently embark upon a wide range of diagnostic investigations; admission to hospital is common. For many years diagnostic scores have been sought to enable reliable exclusion of DVT by simple methods that would readily be adopted by primary care physicians.

The study presented in this issue (2) was carried out in the offices of primary care physicians in the Düsseldorf and Witten areas of North Rhine–Westphalia, Germany. Patients suspected of having DVT were recruited consecutively over a period of 18 months and subjected to a diagnostic algorithm. The authors used the internationally established Wells scoring system to evaluate each patient's risk of embolism. Patients adjudged to be at low risk (Wells score ≤ 1) underwent additional D-dimer measurement by means of a validated rapid office test carried out by the primary care physician. Those with a positive D-dimer result or Wells score >1 underwent further diagnostic investigation, usually compression ultrasonography. After 6–8 weeks the patients were seen again—or at least interviewed by telephone—to check their progress, particularly with regard to DVT or pulmonary embolism.

Of the 310 patients in whom the diagnostic algorithm excluded DVT, three developed a pulmonary embolism in the follow-up period.

The algorithm thus displayed sensitivity of close to 97% and a negative predictive value (NPV) of 99%. In other words, of every 100 patients suspected of having DVT, one had a missed DVT that led to a pulmonary embolism. The physician's subjective assessment was, as expected, less accurate than the algorithm, although the differences turned out to be astoundingly small. Nine cases of DVT were overlooked, yielding

sensitivity of just under 86% and an NPV of 95%, corresponding to five missed DVTs leading to pulmonary embolism per 100 cases. It has to be assumed, however, that the clinical evaluation skills of the primary care physicians trained for participation in the study were more acute than usual.

Testing of the authors' algorithm in clinical practice has thus shown it to possess a high degree of diagnostic accuracy. It will allow the physicians of patients with suspected DVT to dispense with a costly and long drawn out battery of investigative procedures.

Nevertheless, the study displays limitations. For example, DVT with only mild clinical symptoms could have been overlooked because of the lack of standardized diagnostic procedures during follow-up. It is unlikely, however, that any clinically symptomatic DVTs and lung embolisms with relevance for the long-term prognosis were missed.

Unfortunately the authors provide no data on the individual parameters of the algorithm. How high were the sensitivity and the NPV of the Wells score alone? To what extent were they improved by the assessment of a specially trained experienced physician? What additional information was yielded by the—not inexpensive—D-dimer determination? Ultimately, further investigations are needed to identify a cost-effective yet highly accurate procedure for exclusion of DVT.

These limitations notwithstanding, this study marks a sea change with regard to clinical studies. While most earlier investigations were carried out in specialized facilities under conditions far removed from reality, thus excluding a large proportion of the patients seen in routine clinical practice, nowadays the value of “real-life” studies under normal daily conditions is recognized. The necessity of testing diagnostic and therapeutic algorithms and procedures under the conditions of daily clinical practice is becoming increasingly apparent. Other countries are far ahead of Germany in this respect: Primary care physicians have joined together in networks for observational studies and also for clinical testing, because experience has shown that high-quality studies can be conducted within the framework of the law. In Germany, not only physicians but also bodies responsible for health service research at state and federal level have long failed to recognize that medical care benefits from good research under the normal conditions of clinical practice and that any

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office-based physician can take part in this progress. The article discussed here proves that such research yields results relevant to practice. I hope that the authors' work will encourage primary care physicians to participate in such research projects in future.

Conflict of interest statement

The author declares that no conflict of interest exists.

Translated from the original German by David Roseveare.

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