Statistical Final Report Summary

Opossum

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Summary

In this prospectively-designed, non-interventional, epidemiological registry study the data from a total of 651 patients was recorded. 641 of the 651 patients (98.5%) agreed to allow the contracted research institute to contact their treating physician and 92.3% consented to be contacted themselves, should their respective treating physician not be available.

Within the framework of the clinical study, the data of 643 patients was recorded (98.8%). Of these patients, 46.7% were female and 52.7% were male. In the case of four patients, no information regarding their sex was documented (0.6%). The median age at the time of admission to hospital was 69 years of age, median height was 170 cm (approx. 5 ft 7 in), the median weight was 76 kg (approx. 12 stone). The median period of time spent in hospital was seven days.

The most commonly issued primary diagnosis according to the ICD-10 classification was ‘angina pectoris’ for 7.3% of patients, followed by ‘left-sided cardiac insufficiency / failure’ (6.8%) and ‘atrial fibrillation’ (5.8%). The leading secondary diagnosis was ‘benign essential hypertension’ in 10.8% of cases. The main risk factors present in patients included ‘cardiac failure (NYHA III/IV)’, present for almost 30% of patients, followed by ‘extended varicosis / chronic venous insufficiency’ for 20% of patients and ‘tumour’ (17.6%). Furthermore, 11.8% of surgical operations carried out were lapatoscopic surgery; the median duration of all operations was 82.5 minutes and for a total of 98.5% of operations, endotracheal (intubation) anaesthesia was applied.

For a large portion of patients (72.9%), no information on patient mobility was provided at the time of admission to hospital. The remaining patients were mostly classed as exhibiting ‘predominant, but not complete immobilisation’ (56.9%). At the time of discharge, in contrast to the time of admission, only for 1.4% of patients was no information provided and 92.5% of patients had ‘no limitations on their mobility’. In addition, 82.3% of patients received as medication a thromboembolism prophylaxis. For around half of the patients (54.3%), ‘low molecular weight heparin’ was administered. The median duration period for all medication administered was six days. The predominant reason for the non-administration of thromboembolism prophylaxis medication was ‘no indication / no information provided’ (35.1%). In contrast to measures of treatment taken by prescription of medication, only 5.1% of patients were prescribed mechanical measures to contribute to thromboembolism prophylaxis. In 66.7% of cases, these measures involved ‘compression stockings’. The median duration period of all measures taken was seven days. During their time in hospital, only two patients (0.3%) had either a deep vein thrombosis (DVT) or a pulmonary embolism

(PE), whereby one patient suffered DVT and one patient suffered a PE. However, no information was provided on the DVT and / or PE diagnostics.

The hospital discharge letters for 17.6% of patients recommended a medical thromboembolism prophylaxis. For around 75% of patients, the intake of 'vitamin K antagonist (coumarin)' was recommended. Mechanical measures were recommended to 3.7% of patients, which in most cases meant using of compression stockings (66.7%). The median duration period recommended for these measures to be carried out was 161 days.

For 33% of patients, a follow-up consultation took place with their respective treating physician, 19.4% were contacted and surveyed personally and for 47.6% of patients no follow-up of any kind was documented.

Thirty-one of the 212 patients for whom a follow-up took place with their respective physician were re-admitted to hospital (14.6%). In most cases (96.8%), the reason for admission was not specified. No patient died. At the time of being discharged from hospital, almost 25% of patients received recommendation for the continued prescription of a thromboembolism prophylaxis. This recommendation was followed by patients' physicians in 25.9% of cases. The most common medication prescribed in this context was 'vitamin K antagonist (coumarin)' (61.8%). In addition, these measures were continued in more than half of all cases (52.7%). The recommendation for continuation of mechanical measures was followed by patients' physicians in 6.6% of cases, and half of all such measures were continued. In 4.7% of cases, in spite of there being no such recommendation, patients' physicians prescribed a thromboembolism prophylaxis. The most commonly prescribed medication was 'Clopidogrel', and the median duration of prescription was 92 days. In spite of a lack of such recommendation, mechanical measures were prescribed by those physicians of patients whose follow-up took place with their respective physician in 3.8% of cases. Furthermore, only in the case of one patient (0.5%) was there a clinical suspicion of deep leg vein thrombosis or a pulmonary embolism since that patient had been discharged from hospital. The case in question concerned a DVT and the procedure applied in order to confirm the suspicion involved 'duplex ultrasound / sonography' and 'd-dimer testing'.

In the context of a follow-up consultation, a total of 125 patients were contacted and surveyed directly. Of these 125 patients, 40.8% received medication after being discharged from hospital for the prevention of thrombosis. Of this number, 39.2% received tablets and 3.2% received injections. Concerning the tablets administered, in 28.8% of cases Marcumar was prescribed; concerning the injections, the content of the injection was mostly not known by the patients (75%). The median duration for taking tablets was 107 days and for the administering of injections, seven days. Furthermore, 16.8% of patients received thromboembolic deterrent stockings after being discharged from hospital and in 3.2% of

cases a blood clot (thrombus) was discovered, which in 75% of cases was a leg thrombosis. Finally, 32 of the 125 patients (25.6%) who in the context of a follow-up consultation were contacted directly were re-admitted to hospital.

Furthermore it should be mentioned that within the scope of the present study, no serious adverse events (SAE) were documented.