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Original article

Prospective study of catheter-related central vein thrombosis in home parenteral nutrition patients with benign disease using serial venous Doppler ultrasound

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SUMMARY

Background & aims: Catheter-related central vein thrombosis (CRVT) is a severe complication of home parenteral nutrition (HPN) that may be clinically manifest or subclinical. The aims of the study were to prospectively investigate the incidence of CRVT in patients on HPN with benign disease and determine the influence of different variables on this complication.

Methods: A prospective, multicentre, observational study in the Home Artificial Nutrition-Chronic Intestinal Failure ESPEN group was performed. Patients with benign disease starting HPN or already on HPN after the insertion of a new catheter, were recruited and followed up with Color Doppler Duplex Sonography (CDDS) evaluations at baseline, 1 week, 3, 6 and 12 months after catheter insertion. Fisher's exact test was used to calculate the association of different variables (related to the patient, type of catheter, vascular access, insertion method, catheter care and anticoagulant treatment) with CRVT events.

Results: Sixty-two patients (31 males, 31 females) aged 50 ± 19 (19–83) years were included and followed for a median 363 days, with an Inter Quartile Range of 180–365 days, and a total of 16,186 catheter-days. Six patients had previous CRVT and 16 had history of thromboembolic disease (pulmonary and mesenteric). Forty one patients were receiving anticoagulant treatment. Fifty two patients had tunneled catheters and 10 implanted ports. Two patients had symptomatic thrombosis at 3 and 12 months of follow-up (2 and 3 weeks after normal routine CDDS evaluation). The incidence of CRVT was 0.045/catheter/year. CRVT was not significantly associated with any of the variables analyzed.

Conclusions: The incidence of CRVT in patients on HPN for benign disease followed by CDDS is low in the first year of catheterization. We did not observe any case of asymptomatic CRVT. Based on our data, CDDS seems to have low effectiveness as a screening tool for CRVT in asymptomatic patients on HPN with benign disease.

1. Introduction

Thrombotic complications of central venous catheters are dynamic processes with varying severity. They can range from the appearance of the fibrin sheath at the tip of the catheter, to an intraluminal blood clot, mural thrombosis or venous thrombosis [1]. Catheter-related vein thrombosis (CRVT) is a severe complication that is responsible for the loss of central venous access devices

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in patients on home parenteral nutrition (HPN) and may be an indication for small bowel transplantation if it affects two or more of the central venous vessels (subclavian, jugular or femoral) [2]. CRVT may be clinically manifest or subclinical. In retrospective studies, the incidence of symptomatic CRVT in patients on HPN is 0.02–0.09 cases/catheter/yr, with the higher rates reported in children [3–6]. On the other hand, the incidence of subclinical CRVT is unknown in patients on HPN with benign disease.

The pathogenesis of CRVT is multifactorial and includes vessel injury during the procedure of insertion, venous stasis due to indwelling of the device and damage to the endothelium caused by infusion of parenteral nutrition with a high osmolality (high dextrose and potassium concentration), and mechanical rubbing of the catheter against the vessel wall [7,8].

Venous thrombosis can develop soon after catheter insertion or be delayed in patients with long-term catheterization. The former scenario is probably related to the damage to the endothelium of the vein during insertion and may be decreased using ultrasound guidance [9]. Other important factors are the selection of which vein, the catheter and the location of the tip of the catheter either in the lower third of the superior vena cava, at the atrio-caval junction, or in the upper portion of the right atrium [10].

The gold standard method for CRVT diagnosis is venography, but it is invasive and requires exposure to intravenous contrast and radiation. The preferred method for CRVT screening is ultrasonography, which may be employed in both symptomatic and asymptomatic thrombosis as it is a non-invasive method [7]. Duplex ultrasound can accurately detect CRVT involving the jugular, axillary, distal subclavian and the arm veins. Constrast venographic imaging is required for indeterminate duplex findings and to evaluate the deep central veins and pulmonary arteries. In a systematic review, compression ultrasonography had a good sensitivity (97%) and specificity (96%) compared to venography for the diagnosis of clinically suspected upper extremity deep vein thrombosis [11].

The aim of the study was to prospectively study the incidence of CRVT in patients on HPN with benign disease, and secondarily to determine the influence of different variables on the incidence of CRVT.

2. Materials and methods

A prospective, multicentre, multinational, observational study was conducted in the Home Artificial Nutrition-Chronic Intestinal Failure (HAN-CIF) ESPEN group to study the incidence of CRVT in patients on HPN. Five centres in 3 countries participated in the study (France [1], Spain [3] and Italy [1]). The study was performed according to the STROBE statement for cohort studies.

Eligible patients were adults with intestinal failure due to benign disease starting HPN (through a central tunneled catheter or implanted port) or patients already on HPN after the insertion of a new catheter, between October 2009 and December 2011. Catheters were inserted by the same person in each institution under maximal sterile barrier precautions (including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape) and skin preparation with >0.5% chorhexidine preparation with alcohol [12]. Patients were excluded if there was a diagnosis of active cancer (five year survivors who were not being given any cancer therapy and in whom no cancer therapy was planned were included).

After catheter insertion patients were followed up with Color Doppler Duplex Sonography (CDDS) which displays blood flow in color in addition to the gray scale imaging of the ultrasonography. Evaluations were carried out at 1 week, then after 3, 6 and 12 months to explore the appearance of early or delayed catheter-related thrombotic complications. The examinations were performed by the same radiologist/doctor in each centre, according to the standard technique with the Phillips HD11 XE Ultrasound System®.

Symptomatic venous thrombosis was defined as thrombosis of the vein associated with the catheter, manifested as edema and increased filling of superficial veins of the territory drained by that vein. Asymptomatic venous thrombosis was defined as thrombosis of the vein associated with the catheter found during CDDS examination.

The criteria for venous thrombosis in the CDDS were any of the following: absence of vein compressibility, visualization of an intraluminal thrombus (location, extension), flow void on CDDS and dampened, nonpulsatile, and nonphasic flow on duplex sonography.

Patient characteristics (age, underlying disease, months on HPN, previous CRVT, and previous thromboembolic disease), as well as the type of catheter, vascular access, insertion method, catheter care and anticoagulant treatment were recorded.

2.1. Statistical evaluation

Quantitative variables are expressed as the mean ± SD, or median and inter-quartile range (IQR). Categorical variables are expressed as frequencies and percentages. The incidence of CVT is expressed per 1000 catheter-days and per catheter/year. We used the $\chi 2$ test or Fisher's exact test (in those cases in which more than 25% of the cells in the contingency tables have expected frequency less than 5) to study the association between categorical variables. The level of significance was set at 5%. Data were analyzed using the SPSS-21 package.

2.2. Ethical statement

Written informed consent was obtained from the patients prior to inclusion. The study was approved by each local Ethics Committee and written approval was obtained according to national regulations.

3. Results

A total of 62 patients (31 males, 31 females) from 5 centres were included (39 L'hopital Beaujon, France, 17 Hospital Gregorio Marañón, Madrid, 4 Hospital Vall d'Hebron, Barcelona, 1 Hospital

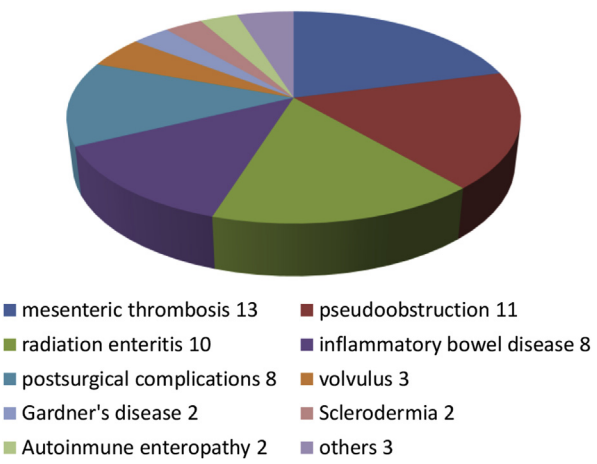

Fig. 1. Patients' underlying disease. (Others group included patients with the apple-peel syndrome 1, sclerosing peritonitis 1, immunodeficiency 1).

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