ORIGINAL ARTICLE

Evaluation of at-home phlebotomy for iron overload: Feasibility and satisfaction of patients and healthcare workers

Saignée à domicile dans les surcharges en fer : enquête de faisabilité et de satisfaction des intervenants


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Summary
Objective. — This study aimed to evaluate at-home phlebotomy and the satisfaction of iron-overload patients and healthcare workers with the procedure.
Methods. — Forty-two patients underwent at-home phlebotomy between 2003 and 2006. The phlebotomy was performed by the patient’s nurse, who was trained by the private healthcare firm that also took charge of the disposal of the blood products. Data concerning these phlebotomies were collected via telephone interviews with all 42 patients, as well as 35 nurses and 40 primary-care physicians. The Limousin Regional Health Observatory processed the data collection.
Results. — Ninety percent (38/42) of the patients, 80% (28/35) of the nurses and 67% (27/40) of the primary-care physicians responded. For 80% of the patients, phlebotomy volume and frequency were as prescribed. Patients chose home phlebotomy for personal reasons, or because of the limited availability of French Blood Establishment facilities (68%), or in response to being offered it by their hospital physician (32%). For 81.6% of the patients, at-home phlebotomy was more satisfactory than phlebotomy in hospital or at the French Blood Establishment and, for 84%, the constraints required were fully acceptable. The nurses considered that these homecare procedures were within their area of responsibility (100%), but felt that the remuneration was
Introduction

In 2005, the French Superior Health Authority (HAS\(^1\)) recommended at-home phlebotomy for patients with hereditary hemochromatosis to reduce healthcare expenditures and to improve patient compliance.

If left untreated, the natural history of iron overload leads to complications that affect the patient’s quality of life and may even be life-threatening [1]. Phlebotomy is the primary treatment for hereditary hemochromatosis and can also be used for dysmetabolic hepatosiderosis, although the beneficial effect in this case remains theoretical and requires further, prospective study [3].

Undesirable effects due to phlebotomy are minimal. The French Blood Establishment (EFS\(^2\)) has unpublished data concerning minor incidents in 0.39% of cases, mostly involving first-time blood donors [4]. Phlebotomy is also the least costly method of reducing iron overload. Iron chelators are reserved for patients who are contraindicated for phlebotomy and cannot be used in the general population because of their cost and toxicity.

A recent survey demonstrated that the majority of liver-disease specialists prescribe phlebotomy either in hospital (63%) or in an outpatients setting (16%) or within the framework of blood donation (22%) or homecare (9%) [5]. Nurse availability in most outpatients clinics is insufficient to allow for the 20 to 30 min required for a phlebotomy. In addition, the current regulations in France require a physical (geographical) separation between facilities for donor blood procurement and therapeutic phlebotomy. It has also been noted that patients are apparently more willing to accept at-home phlebotomy when faced with the logistical problems resulting from a shortage of available healthcare personnel or a geographical distance that makes it difficult to visit a hospital or donor center regularly, especially during the period of induction. The HAS also suggests that phlebotomy could be performed in medical laboratories, but there are scant data in the literature concerning this option and it still would not solve the problem of geographical distance or availability of qualified personnel. At our center, at-home phlebotomy has been available since 2003 as a response to organizational problems, patient requests and increasing demand. Yet, in our region and despite the availability of at-home phlebotomy, the number of phlebotomies performed by blood-donor facilities has increased steadily from 515 in 2000 to 969 in 2006.

The purpose of our survey was to study the feasibility of at-home phlebotomy in terms of concordance between prescription and execution, patient compliance and safety and tolerance, as well as the level of satisfaction of both the patients and healthcare personnel.

Patients and methods

Study set-up

This was a retrospective non-comparative survey conducted after the HAS recommendations for at-home phlebotomy were issued, but involves phlebotomies performed in patients’ homes from 2003 to 2006, before the recommendations were published. Patients, nurses or physicians who performed the phlebotomies, and the patients’ primary-
care physicians were asked to respond to a telephone interview validated by specialists from the Limousin Regional Health Observatory, who recorded the collected data. The blood-donor centers that performed most of the phlebotomies not carried out in patients’ homes also contributed their data.

Patients

At-home phlebotomy was first proposed for patients living far from donor centers that had limited opening hours or personnel shortages. When it was apparent that this proposal was favorably accepted by patients, and after checking for compliance with detailed organizational criteria, at-home phlebotomy was routinely proposed for all patients free of contraindications (as defined by the HAS). Phlebotomies were still performed at blood-donor centers for patients who declined the at-home procedure.

Survey questionnaire

Telephone interviews were conducted by clinical research assistants who were not involved in the at-home phlebotomy process. The data collected included, from:

- patients:
  - duration of iron-overload-depletion therapy and time since starting at-home phlebotomy;
  - number of phlebotomies performed;
  - type of procedure used by the nurse or physician for the phlebotomy;
  - time spent by the healthcare professional in the patient’s home;
  - duration of the phlebotomy;
  - materials used;
  - incidents;
  - advantages and disadvantages of the at-home procedure;
  - medical follow-up;
  - results of complementary tests.
- Healthcare personnel:
  - modalities used for phlebotomy; materials used;
  - problems encountered;
  - commitment to the at-home process and relationship with the patient;
  - relationships with medical and allied personnel, and need for accompanying support;
  - general feeling about this type of treatment;
  - opinions concerning the remuneration proposed.
- Patients’ primary care physician:
  - involvement in the management scheme;
  - adequacy of information received;
  - opinions concerning a possible partnership contract.
- Limoges blood-donor center (EFS):
  - modalities used for phlebotomy;
  - duration of phlebotomy;
  - materials used;
  - incidents;
  - perception of phlebotomy within the framework of the center’s general activities.

Practices used for at-home phlebotomy

In our experience, most patients who required treatment for iron overload had type 1 hereditary hemochromatosis or dysmetabolic hepatosiderosis. Among those with dysmetabolic hepatosiderosis, phlebotomy was performed when iron overload exceeded 100 μg/mL (as measured by magnetic resonance imaging). Patients had at least three phlebotomies during a three-week induction period in an institutional setting before starting at-home phlebotomy. The patients chose the nurse who was to perform their phlebotomies at home. A private firm, ALAIR&AVD, was in charge of the at-home phlebotomy. This firm trained the nurses who performed the phlebotomies, furnished the materials necessary for the procedure and managed the information systems (patients’ files completed by hospital physicians, exchange of information between the outpatients and in-hospital teams). In addition, ALAIR&AVD provided a 24-hours-a-day, seven-days-a-week backup system so that patients and nurses could contact an allied healthcare professional if necessary. The patient was given special containers for the blood products and the used materials. After each phlebotomy, the nurse deposited the blood products into the containers, which were collected regularly by ALAIR&AVD for disposal according to regulatory requirements.

Two blood-withdrawal kits (negative-pressure bottle, tubing, butterfly needle) were used successively (Fig. 1). The system was designed to enable safe and easy blood withdrawal: sufficiently rigid tubing to avoid collapse; negative-pressure collection bottle to facilitate blood outflow; and intermediate-diameter needle to facilitate blood flow with minimal damage to venous tissue.

At each phlebotomy, the duration of blood withdrawal, volume of blood withdrawn, heart rate and blood pressure, as well as any undesirable events were recorded in the patient’s file. Blood pressure and pulse were recorded before starting blood withdrawal, when half of the blood had been withdrawn (on average, about 10 min after venipuncture) and at the end of the procedure.

Patients receiving acute treatment attended a specialist consultation every three months. In accordance with the HAS recommendations, serum hemoglobin and ferritin test results were faxed to the specialist prescriber, who adapted the timing and volume of the phlebotomy as necessary.

All patients on long-term treatment attended consultations annually or every two years, depending on their disease severity. Serum hemoglobin and ferritin were assayed before each phlebotomy. These tests were ordered either by the primary-care physician or by the hospital center, depending on the patient–physician relationship. Controls were the same for patients whose phlebotomies were performed at home or in a hospital setting.

Results

Home phlebotomies were performed for 42 patients between 2003 and 2006; 35 nurses, two executing physicians and 40 primary-care physicians were asked to participate in telephone interviews. Twelve patients who had phlebotomies at home within the context of home hospitalization were not included in the analysis.
At the time of our study, 88% of the study patients resided in the Limousin region, 69% within the administrative district of Haute-Vienne and 50% in the Limoges urban area. The response rate was 90% (38/42) of the patients, 80% (35/35) of the nurses and 67% (27/40 of the primary-care physicians.

Responses from patients

Thirty-eight patients responded — 16 women, 22 men — mean age 55.9 ± 12.1 years, age range 36—80 years. Fifteen patients had type 1 hereditary hemochromatosis (group 1). The others (group 2) had dysmetabolic hepatosiderosis (n = 19), chronic hepatitis C (n = 4) or porphyria cutanea tarda (n = 1). Serum ferritin levels were initially 1220 ± 1079 ng/mL in group 1, and 801 ± 395 ng/mL in group 2.

A total of 591 at-home phlebotomies were performed, including those carried out during an induction phase (one per week or two per month) (n = 29) or as part of long-term maintenance therapy (one phlebotomy every two to six months) (n = 38), by the nurse chosen by the patient and trained by ALAIR&AVD, and across six administrative districts (68.4% in Haute-Vienne, 10.5% in Corrèze, 7.9% in Creuse, 5.3% in Dordogne, 5.3% in Charente and 2.6% in Haute-Garonne) (Fig. 2). The mean serum ferritin levels in patients at the end of the induction phase was 37 ± 25 ng/mL in group 1 and 102 ± 40 ng/mL in group 2.

Two patients encountered difficulties in finding a nurse willing to perform the phlebotomy. One of these patients, who resided in a rural area in Corrèze, reported that nine nurses had declined for reasons of safety and wages. On average, patients had phlebotomy treatment for 39 months (Fig. 3), including 17 months at home (Fig. 4). Sixty percent of patients received at least 10 phlebotomies at home, and 58% had started home phlebotomy less than 30 days after starting iron-depletion treatment (Fig. 5).

Phlebotomies performed at home withdrew, on average, 414 ± 54 mL in 20 ± 7 min. Phlebotomies were carried out at the prescribed frequency in 78.9% of patients. Several scheduled phlebotomies were not done in one patient, and one or two phlebotomies were missed in seven patients. The reasons for these were the following:

- personnel unavailable (n = 3);
- nurse unavailable (n = 1);
Incomplete phlebotomy occurred in 20 patients for the following reasons:

- tubing obstruction \( (n = 12, 60\%) \);
- patient’s decision that the ferritin goal had been reached and that the phlebotomies should be stopped \( (n = 2) \).

The procedure was considered nearly pain-free by 81.6% of patients. Events noted were as follows:

- malaise \( (n = 1) \);
- episode of hypotension \( (n = 2) \);
- hematoma at the puncture site \( (n = 4) \).

The materials used were generally well accepted and most of the problems were related to the type of needle or tubing used (collapse). Patients chose at-home phlebotomy because they lived far from a blood-donor center or hospital (31.6%), because of an organizational problem (center opening hours, occupational reasons; 36.8%) or because it was proposed by their specialist (31.6%). The majority of patients (81.6%) felt that at-home phlebotomy was more satisfactory than hospital or blood-donor-center procedures and 84% accepted the constraints well (Fig. 6). Seventy-nine percent of patients were satisfied with the timing of their specialist consultations. The patients’ files were correctly completed by the nurse in the majority of cases (89.5%).

At the end of the study, 27 patients (71.1%) were still having at-home phlebotomy and 11 patients no longer requi-
red treatment. Among the 27 patients, 96.3% stated they would continue the at-home method; in addition, 97.3% of the patients questioned said they would recommend having at-home phlebotomy.

Responses from executing nurses and physicians

Eighty percent (28/35) of the nurses and one executing physician (1/2) responded (n = 29): 24 (83%) had practised home phlebotomy for more than six months; and 14 (50%) stated they were “at ease” with the method after the second procedure. Twenty-one nurses had encountered problems and recorded a total of 31 incidents (Fig. 7).

Ninety-three percent of the nurses considered the materials furnished in the kit were satisfactory and used them regularly. Two nurses used their own materials, one out of preference and the other because the materials were considered unsuitable. Instead, these nurses used a larger catheter (n = 2), simple tubing (n = 1), a normal-pressure rigid bottle (n = 1) and a collection pouch (n = 1).

Ninety percent of the nurses were aware of the procedure to follow in the event of a problem (malaise, technical incident) and felt that a written protocol was useful. Seven nurses (24%) asked for outside advice to deal with a materials problem: two nurses called a physician once and five nurses called the ALAIR&AVD coordinating nurse once during a phlebotomy.

All of the nurses considered that they were responsible for the procedure and that the process was emotionally satisfying, enabling a true patient—caregiver relationship despite the fact that 41.4% felt that the first time they did the procedure was stressful. Twenty-five nurses (86%) felt that the procedure should be considered part of the area of competence of nurses and 76% agreed to provide care for more than one patient (two or three). The remuneration, 26.50 euros, was considered insufficient by 65% of the nurses.

Responses from non-executing physicians

Sixty-seven percent (27/40) of the primary-care physicians who did not execute the phlebotomies responded: 96% (26/27) had been informed that their patients were receiving at-home phlebotomy, 12 by the specialist who had prescribed the procedure and 12 by the patient. Only 42% of the primary-care physicians were directly involved in the management of the procedure.

Eighty-nine percent of the primary-care physicians wanted information on hemochromatosis and other iron-metabolism disorders that required phlebotomy: 56.5% wanted a brochure or CD, and 26%, a continuing-education training session. More than half of the physicians desired practical training in phlebotomy (55.5%) and were willing to perform the at-home procedure.

Of the primary-care physicians, 77% were willing to establish a contract with the healthcare professionals involved (prescribing specialist, private-practice nurse, managing firm), although 44% wanted to discuss the terms and conditions.

Responses from the Limoges blood-donor center (EFS)

In 2005 in the Limousin region, the Limoges blood-donor center (EFS) performed 775 therapeutic phlebotomies. The EFS practitioners who were questioned (two physicians and one nurse) considered that therapeutic phlebotomy was a procedure included in the center’s remit and that it provided a genuine service to the patients. Furthermore, they believed that the procedure enabled practitioners to establish a stronger relationship with their patients. In most cases, the phlebotomies were scheduled and generally took about 30 min.

Due to organizational restrictions requiring that therapeutic phlebotomy and blood donation not be done concurrently at the same location, since 1998, the Limoges EFS is available only two days a week (11 h) for therapeutic phlebotomy. Several patients have complained about this restriction.

Phlebotomy performed at the EFS is done using the same materials as for blood donation (dry pouch with incorporated needle). The volume collected can be difficult to evaluate due to the use of an agitator. The problems encountered are essentially related to venipuncture (precarious venous
tissue, overly large needles). In a small number of patients, phlebotomy is sometimes incomplete or impossible. However, the blood-withdrawal system used by the EFS (dry gravity pouch) is poorly adapted to the use of smaller needles.

The most frequent incidents reported by the EFS are malaise, hypotension and hematoma at the puncture site.

**Discussion**

Therapeutic phlebotomy is the first-line treatment for hereditary hemochromatosis. Recent advances in the genetics of iron overload, national screening campaigns and the 2005 recommendations of the HAS for the therapeutic management of hereditary hemochromatosis have greatly improved screening performance. It should be noted, nevertheless, that the HAS recommended at-home phlebotomy without detailing the practical issues involved.

When phlebotomy is performed outside the patient’s home, it is usually performed in an outpatients or blood-donation setting. The duration of the procedure (about 30 min) is the same, but the patient has to get to the center. The experience of blood-donor and outpatients personnel is clearly an advantage, particularly in terms of safe disposal of the blood products. But this has to be balanced against the lack of personnel for hospital consultations. In addition, the most recent legislation in France has required a physical (geographical) separation between sites of blood donation and therapeutic phlebotomy. This legal restriction prohibits an “open door” policy at blood-donation centers (EFS). The materials used by these centers are designed for blood donation and, although effective, they are somewhat old-fashioned (large needle, gravity pouch), raising a long-term problem of venous tolerance. Phlebotomy could also be performed at medical laboratories but, to our knowledge, there are no data on this option.

We proposed at-home phlebotomy back in 2003. The main problem with the at-home procedure is safe disposal of the blood products. Initially, there was also the question of whether or not private-practice nurses would be willing to perform the procedures. To overcome these obstacles, we worked with the private firm ALAIR&AVD, which is in charge of managing the at-home phlebotomies on a non-profit basis. ALAIR&AVD has played a crucial role in the development of the practicalities related to at-home phlebotomy in the Limousin region.

This study was a retrospective non-comparative analysis of the feasibility of at-home phlebotomy, as performed before and after the HAS recommendations. The satisfaction of the various participants was also evaluated. Except for medical contraindications, the patient’s own decision to have at-home phlebotomy was the only selection criterion. Although the study population appears to be well balanced for many variables, the fact that inclusion was totally voluntary limits the possibilities of extrapolating the results to the general population.

Our survey demonstrated that at-home phlebotomy throughout our region performed in this population under the described conditions is feasible, irrespective of patient age or treatment phase (induction, long-term maintenance), and can be rapidly instituted (in less than one month). The mean duration of the procedure was 20 min, although the presence of the nurse was required for about 30 min. These times are comparable with those at blood-donor centers, excluding the time taken for patients to travel to and from the center. Patients preferred the at-home over the institutional scheme. There might be a subjective bias related to the fact that the first phlebotomy (always performed in an institutional setting) tends to be more stressful than the subsequent phlebotomies.

All of the nurses considered the procedure satisfactory in itself, and pointed out the importance of the patient relationship aspect. About 40% of the nurses felt that the first phlebotomy was stressful for them, suggesting that more support might be useful. This could involve increasing the number of phlebotomies performed jointly with the ALAIR&AVD nurses or the implementation of theoretical training sessions. A written protocol outlining the phlebotomy and the procedure to follow in case of an incident was considered indispensable. The protocol is explained at the initial training session in the patient’s home, and formalized as a guide given to each nurse. Despite these measures, 10% of the nurses appeared to be unaware of the correct procedure to follow. A general training session for private-practice nurses, with a practical demonstration, could help to bolster the information delivery.

The prevalence of adverse events during at-home phlebotomy procedures was lower than reported by Adams [6]. Several cases of local venous infection were reported. None of the patients developed anemia [6].

Remuneration for at-home phlebotomy should be increased. At present, the cost of a phlebotomy to the French healthcare fund is 609 euros when performed in hospital (GHM hemochromatosis), 25.50 euros at a blood-donor center (EFS) and 14.50 euros during a hospital consultation (plus the physician’s fee of 21 euros in some cases). In addition to these costs, there is also the additional cost of transportation that, for an average distance of 100 km (round trip), is about 28 euros for a private vehicle and 90 euros for a medical-assistance vehicle. The current cost of at-home phlebotomy to the French healthcare fund is 26.50 euros (14.50 euros for the nursing input, 2 euros for travel expenditures and 10 euros for materials). This means that the cost of an in-hospital phlebotomy is 23 times greater than an at-home phlebotomy, the cost of the management firm being zero (Table 1).

Given these facts, it would appear to be reasonable to increase the nurse’s fees and to pay the management firm. Such changes in remuneration would need to be discussed with the health authorities (Table 2).

The response rate among primary-care physicians was low (65%), despite several phone calls. In general, general practitioners are not involved in the management of at-home phlebotomy, and the majority requested scientific and practical information on the subject. Thus, at the present time, it would be unrealistic to ask GPs to be permanently available for at-home phlebotomy.

The French blood-donor system (EFS) currently plays an important role in the management of patients with iron overload, as therapeutic phlebotomy is among its remit. Unfortunately, the legal restrictions imposed since 1998 and the fact that some patients live a considerable distance from a blood-donor center compromise patient compliance to the treatment schema, and often increase the risk of professional absenteeism. The experience acquired at blood-donor
centers could be usefully applied to training nurses performing at-home phlebotomy, and to choosing the optimal materials to be used by private firms for blood withdrawal and disposal of blood products.

In conclusion, at-home phlebotomy is a feasible technique that reinforces patient compliance to treatment and improves patient comfort. The satisfaction survey shows that 80% of patients consider this method to be better than phlebotomy in an institutional setting. The costs are also 23 times less than for the same procedure performed in a hospital setting or blood-donor center if patients’ transportation is taken into consideration. Improved remuneration of nurses performing at-home phlebotomy would encourage their participation. The services provided by a private firm to ensure the initial training of nurses and a telephone backup scheme, as well as the disposal of blood products, should be better recognized and remunerated to facilitate the spread of this type of healthcare service throughout France. There is also a need for in-depth reflections concerning the realistic commitment of general practitioners to the at-home management of patients with iron-overload disorders.

#### References


