



## Review

## The Italian registry of therapeutic apheresis – 2015



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## ABSTRACT

Data collection on apheresis activities in Italy throughout 2015 including techniques, clinical indications and adverse effects was performed by means of a SidEM model questionnaire (aggregate data). These data provided by 67 Apheresis Units from 17 Italian regions, albeit rough, are sufficiently informative, mainly in comparison with previous surveys on these statistics. PEx has been the most frequent technique for plasma removal/treatment (11787 procedures) followed by LDL-apheresis (927 procedures). ECP/photopheresis has been the most frequent cytapheresis procedure: 6,606 session, mainly by using the off-line technique. Main indications for therapeutic apheresis are neurologic diseases, thrombotic microangiopathy and solid organ transplantation humoral rejection. The apheresis support activity to haematopoietic stem cell transplantation, the PBSC collection has been documented by 53 center: 3254 procedures in 2259 patients. Over all results have been positive: over 80% get better with therapy. Adverse effects, predominantly mild ones (i.e., paresthesia due to citrate-induced hypocalcemia), occurred in 7.9% of therapeutic sessions, of which only 83 have been classified as severe (0.4%).

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## 1. Introduction

In Italy therapeutic apheresis (TA) activity is mainly performed in Blood Transfusion Services and, to a lesser extent, in Haemodialysis Units. Two Scientific Societies are involved in this activity, i.e. the Italian Society of Haemapheresis and Cell Manipulation (SIDEM) and the Italian Society of Nephrology (SIN), but most of apheresis procedures are carried out by professionals who are enrolled to SIDEM.

In fact, the Italian Registry of TA has been managed by SIDEM since the '90s [1]; the Registry also included all the productive activity (mainly plasma and platelets).

Data collection included:

- Type and number of procedures
- Number of treated patients

- Type of blood cell separator (including model and trademark)
- Clinical indications
- Type and number of adverse events.

In 2000, 67 Italian TA Units performed and registered 15,202 apheresis procedures [2]. Plasma exchange (PEX) was the most frequent treatment (7496 procedures) and neurological diseases were the most commonly treated diseases. Severe complications occurred in 0.89% of TA procedures and in 0.06% of peripheral blood stem cell (PBSC) collections.

SIDEM and SIN have carried on a cooperative activity for several years in order to plan a single National TA Registry. Even though with poor compliance by those who compiled it, in 2010 and 2011 single data collection model shared by the two Scientific Societies has been adopted.

The collection model proposed by SIN follows in setting the International Registry of Apheresis: it is filled out online, using substantially the same fields, it does not provide in the final balance of activity, but it consists of progressively cumulative data by identify-

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**Table 1**  
N. of therapeutic procedures performed in Italy from 1997 to 2013.

| Year          | 1997 [1]          | 2000 [2]          | 2005 [3] | 2009 [4] | 2010 [5] | 2012 [6]          | 2013 [7]          |
|---------------|-------------------|-------------------|----------|----------|----------|-------------------|-------------------|
| N° Procedures | 11,907            | 15,202            | 20,450   | 31,909   | 10,274   | 19,712            | 20,896            |
| N° TA Units   | n.a. <sup>a</sup> | n.a. <sup>a</sup> | 59       | 90       | 34       | n.a. <sup>b</sup> | n.a. <sup>b</sup> |

<sup>a</sup> n.a. Not available: data collection also included the apheresis centers donor (plasma collection, platelet collection).

<sup>b</sup> n.a. Not available: the registry also included the Italian society of nephrology data, which now can are not used for privacy reasons.

ing each case by a code. This fact, when considering high activity TA Units, proved an onerous task, so that later SIdEM was compelled to introduce a different model, with a collection of aggregate data.

Recently, the Italian Privacy Authority (IPA) has delivered a negative opinion regard the “old model” of Registry, since it does not rule out a possible identification of patients, namely a critical issue that does not arise in case of aggregate data. At the same time the IPA raised the still not resolved question, whether the TA Registry can be managed by a Scientific Society, or rather it should be under the responsibility of the regulatory authority.

In the period 1997–2013 the TA activity was monitored with a variable response over time from the Italian Apheresis Units (Table 1).

In 2015 the data collection has been performed by the recent SIdEM model (aggregate data), which does not pose privacy concerns, is simple to be filled, and is often based on statistical data already present in the recordings of each Apheresis Unit.

Purpose of the Italian Registry of SIdEM is not only to survey apheresis activities, but also to observe periodically a reality that over the years has changed owing to new technologies, clinical indications and applications, and that everyday has to deal with new options, both technological and/or pharmacological. On the other hand, we are also conscious that the compilation of this Registry still constitutes a hard burden of work, in addition to the compilation of a lot of documents, as routinely requested by some regulatory institutions, such as National Blood Registry and Haemovigilance System reports, besides economic analysis making use of analytical accounting. For this reason a sufficiently exhaustive model has been prepared, at the same time simple and quick in filling.

In fact, the form required the following data for each Apheresis Unit:

- Number of procedures, number and type of blood cell separators (trademark and model, year of acquisition)
- Number of physicians and nurses dedicated to apheresis activity
- Apheresis techniques in use
- Treated diseases (number of patients procedures), according to the ASFA category
- Other diseases treated (not included in the ASFA guidelines)
- Patients outcome (remission, improvement, no change, worsening) according to type of procedure and disease
- diseases for which the collection of PBSCs, extracorporeal photochemotherapy (ECP)/photopheresis or cytoreductive leukapheresis are requested,
- Complications of apheresis procedures, classified as mild, moderate and severe.

## 2. Results

The 2015 Italian TA Registry has been compiled by 67 Apheresis Units, belonging to Blood Transfusion Services from 17 Italian Regions, according to territorial distribution (North, Central, South/Insular). Data are reported in Table 2 with respective technological equipment.

In 2015 overall 27,476 TA procedures (5209 patients) were performed: 595 sessions, in 31 Units, were made on 266 patients as an

urgency/emergency, in some cases regarding paediatric patients (4 Units).

PEX has been the most frequent technique for plasma removal/treatment (11,797 procedures), followed by LDL-apheresis (927 procedures) (Table 3).

As regards cytoapheresis, besides ECP/photopheresis whose details will see later, the most used procedures have been red blood cell exchanges (RBC-Ex), applied mainly in patients with sickle cell disease developing vasoocclusive complications. In Italy migratory flows and international adoptions cause a great increase of people suffering from such haemoglobinopathy, which accounts our Registry data, i.e., 276 patients treated with 1290 RBC-Ex procedures.

Adsorptive cytoapheresis, or granulocyte–monocyte adsorptive (GMA) apheresis, is a procedure that can be applied in non-responder patients or in case of contraindications to the conventional treatments of inflammatory bowel diseases, particularly ulcerative colitis. Since it is a simple treatment from a technical viewpoint, GMA apheresis is often performed in Gastroenterology Units, so it can be assumed that our Registry data, albeit significant (1183 procedures in 161 patients), are underestimated (Table 4).

ECP/photopheresis has been the most frequent cytoapheresis procedure: 6606 sessions, mainly by using the off-line technique (5179 procedures). Clinical indications have been cutaneous T-cell lymphoma/Sezary's syndrome, acute and chronic graft versus host disease (GVHD), solid organ transplantation chronic rejection, but some experiences in the treatment of autoimmune diseases have been quoted (Table 5).

Main indications for therapeutic apheresis treatments are shown in Table 5.

As in years past, neurologic diseases, i.e., myasthenia gravis (MG), chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) and Guillain-Barré syndrome (GBS) have been the most common diseases, involving 614 patients who underwent 4517 procedures.

New neurological syndromes have been also included: indeed, 75 patients suffering from autoimmune encephalitis have been treated with 434 PEX sessions.

Also TTP cases (192 patients), namely an increased number as compared to previous surveys, have been treated, with 2110 PEX procedures.

Relevant has been the use of apheresis treatment of solid organ transplantation humoral rejections, namely 113 patients who underwent 780 procedures. In the VI tab appears clear that most diseases were treated with plasmaexchange or plasma treatment, however we think that in this table should be present also chronic inflammatory bowel disease, which are treated with GMA, because now it has a valid support in therapeutic apheresis.

Included in “others diseases” (Table 6), there have been neurological diseases (status epilepticus, neuromyotonia, transverse myelitis), drug intoxication, mushrooms poisoning, Lyell's syndrome, and rhabdomyolysis).

As regards the apheresis support activities to haematopoietic stem cell transplantation, with reference mainly to the PBSC collection, this activity has been documented by 53 Apheresis Units. The total number of procedures has been 3254 in (2259 patients): PBSC collections have been performed mainly for patients affected

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