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The French Cochlear Implant Registry (EPIIC)

The French Cochlear Implant Registry (EPIIC): General indicators

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ABSTRACT

Cochlear and brainstem implants have been included on the list of reimbursable products (LPPR) in France since March of 2009. The implants were initially inscribed for 5 years, after which an application for renewal with the French National Commission for the Evaluation of Medical Devices and Health Technologies (*Commission Nationale d'évaluation des dispositifs médicaux et des technologies de santé* – CNEDiMTS) was required [Haute Autorité de santé, 2009]. Upon registration to the list of reimbursable products, the companies and the reference centers for cochlear and brainstem implants were asked to set up a post-registration registry called EPIIC. This article reports the evolution in the EPIIC registry of the general indicators for 5051 patients over the five years from 2012–2016.

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1. Material and Methods

The EPIIC registry was implemented according to the following principles:

- definition of the scope;
- establishment of governance;
- financing rules between manufacturers;
- data quality control and data protection;
- establishing regular reports and presentations of EPIIC data.

2. Definition of scope and establishment of governance of the EPIIC registry

The reference centers (the recommended constitution of which was detailed by HAS in 2009) met to elect a scientific committee and its president. This committee is the governing body of EPIIC. An annual meeting with all the centers is organized to discuss the registry over the previous year and to define any new directions or corrective actions. The scope of the registry was defined on the basis of the 2009 initial reference document [1,2], which was modified in 2012 [3]. These include guidelines exploring different fields:

- respect of the guidelines and monitoring of the benefit: guidelines (word intelligibility < 50% at 60 dB SPL in best aided conditions, incapacitating fluctuations of hearing), service rendered (intelligibility score with mono- or di-syllabic words presented at 60 dB SPL under the best aided conditions before and after implant, audiometry with background noise for bilateral implantations). CAP and SIR scores are taken for children before and after cochlear implantation [2,3],
- questionnaires (APHAB or GBI),
- surgery: total or partial insertion, explantation, minor or major complications.

3. Financing rules between industrial partners

The EPIIC registry is managed by the Popsicube clinical research organization (Montigny le Bretonneux,78180, France). This organization allows for independent management. Industrial financing is based on their respective market share. Each structure therefore funds the registry in proportion to their sales.

4. Quality control of data and their protection

Data quality control is an essential element of registry quality. A significant initial completeness (> 0%) is essential for the clinical data to be representative. The completeness check is done by comparing two external indicators (warranty forms returned to companies and data from the French medical systems database [*PMSI – programme de médicalisation des systèmes d'information*]). This comparison, linked to quarterly reports, helps maintain the centers' motivation and completeness. It is also thanks to the initial completeness of entry in the registry that the theoretical follow-up scores can be calculated, which are then compared to the actual patient monitoring scores. Data quality is verified by providing selected indicators to the scientific committee and by site visits from the Popsicube clinical researchers who undertake the quality control of selected files.

The following are the selected general indicators:

- number of implanted children under the age of 12 months, between 12 and 18 months and between 18 and 24 months;
- number of simultaneous bilateral implants among implanted children aged under 12 months, between 12 and 18 months and between 18 and 24 months;
- number of sequential bilateral implants among implanted children aged under the age of 12 months, between 12 and 18 months and between 18 and 24 months;
- indication of age at first and second implantations;
- number of implanted patients between 65 and 75 years old and over 75;
- delay to bilateralization;
- number of explantationsv
- overall number of adults and children who received unilateral or bilateral: simultaneous or sequential implants; sequential implantation is defined as bilateral cochlear implantation with placement of the second implant more than 6 months after the first.

Table 1
Completeness of the registry.

	2012	2013	2014	2015	2016
Exhaustivity	96%	95%	95%	92%	90%
1-year follow-up	79%	78%	74%	66%	61%
3-year follow-up	47%	38%	37%	23%	NA

Data is entered in an electronic notebook on the internet via a dedicated electronic case report form (eCRF). The database is reported to the authorities in charge and its protection is provided by Popsicube (authorized by the French Commission on Informatics and Liberty (*Commission Nationale de l'informatique et des libertés – CNIL)* on April 11, 2011: authorization n° 1477021).

5. Provision of regular reports and presentation of EPIIC data

A quarterly report with general results is sent to each center. An annual meeting, in which each center participates, is organized to present the global data of the year and to discuss desired or necessary developments for the EPIIC registry.

6. Results

During the 5-year study period (2012–2016), the initial completeness averaged 93.6% [min = 90%; max = 96%] compared to the PMSI data. The average rate of follow up, after 1 year, with respect to this initial completeness was 71.6% [min = 62%; max = 79%]. After 3 years the figure is 36.25% [min = 23%; max = 47%] (Table 1).

Five thousand and fifty one patients were registered in the EPIIC database during the reported 5-year period. A total of 81% of patients (4109 patients) received unilateral implantation. Of the remaining 19% (942 patients) that received two implants, 7% (352 patients) were implanted in both sides at the same time, and 12% (590 patients) had sequential implantations (see Fig. 1 for the evolution between 2012 and 2016).

For children implanted unilaterally before 24 months, the most represented age group was between 12 and 18 months (53% of children implanted). The repartition is similar in the simultaneous group with 16% of implantations in the age group under 12 months, 47% between 12 and 18 months and 37% between 18 and 24 months. For the sequential group, the most represented age group for the first implant is between 12 and 18 months (51%) and for the second one between 18 and 24 months (88%).

For children under 24 months, during this period, 320 children were unilaterally implanted and 295 had bilateral implants: 129 simultaneously and 166 sequentially (Table 2). For the sequential group, the bilateralization time was 18 months on average

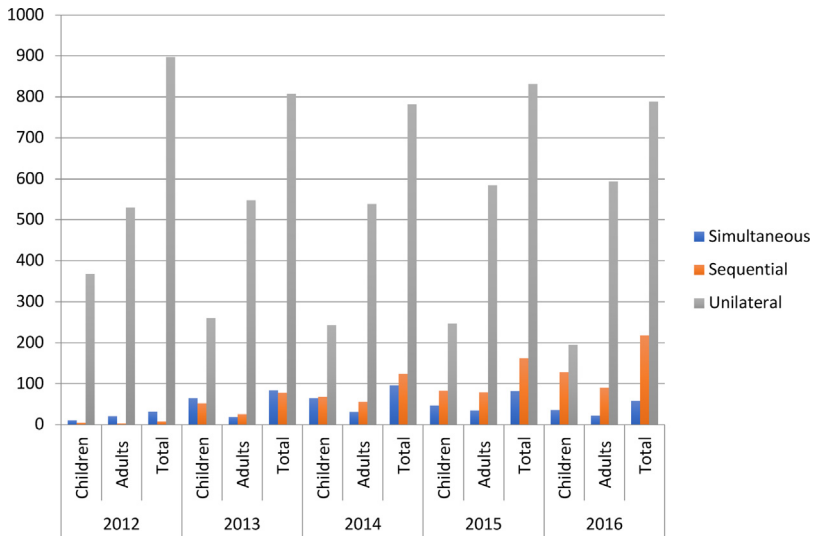

Fig. 1. Evolution and repartition of the cochlear implantations in the registry.

Table 2
Evolution of the cochlear implantations in children.

Unilateral						
Age	2012	2013	2014	2015	2016	Total
≤ 12 months	5	7	9	3	17	41
> 12 & ≤ 18 months	22	25	35	38	50	170
> 18 & ≤ 24 months	22	17	17	23	30	109
Simultaneous bilateral						
Age	2012	2013	2014	2015	2016	Total
≤ 12 months	2	5	6	4	3	20
> 12 & ≤ 18 months	2	19	15	13	12	61
> 18 & ≤ 24 months	3	15	12	12	6	48
Sequential bilateral						
Age at first implantation	2012	2013	2014	2015	2016	Total
≤ 12 months	11	2	3	9	4	29
> 12 & ≤ 18 months	25	18	11	24	7	85
> 18 & ≤ 24 months	16	11	15	8	2	52
Age at second implantation	2012	2013	2014	2015	2016	Total
≤ 12 months	0	0	0	0	1	1
> 12 & ≤ 18 months	0	0	1	2	2	5
> 18 & ≤ 24 months	8	5	6	19	8	46

(minimum: less than 1 month, maximum: 50 months, median: 15 months, SD: 11 months).

The number of explantations varied between 8 and 33 cases/year with the most occurring in 2015.

During the study period, 1195 implanted patients were over 65 years of age, including 726 patients in the 65–75 age group and 469 over 75s (see Fig. 2 for the evolution between 2012 and 2016).

7. Discussion

The target of completeness desired by the centers was that it be over 90%. During the period concerned, it has always been higher than this value. This indicator is a major component of registry quality, especially when studying the occurrence of complications and most especially when complications are rare [4]. The control of implanted patients incorporated in the registry may in the future be further improved by cross-referencing with other medical/administrative databases, for example the DIAMANT (*Décisionnel Inter-ARS pour la Maîtrise et l'ANTicipation des Agences régionales de santé*) database. One can however consider that the EPIIC registry, with a follow-up rate of over 90% of implanted patients, already allows a relevant appraisal of the occurrence of complications or adverse effects. A moderate trend over time towards decreasing completeness should however be noted. This is doubtless due to the increased workload accompanying successive increases in cohort size, without changes in the regular surveillance tasks that the teams accomplish on the adult and child patients. For example we could legitimately ask ourselves if it is necessary to continue follow-up on adult implanted patients who adapt well to the intervention over the first year. The resources devoted to this monitoring could be reallocated to other patients, such as children generally or adults with poorer or declining performance. This new monitoring scheme could also partially benefit from telemedicine, eventually even with self-testing [5–7].

Since 2012, bilateral cochlear implantation has been reimbursed for adults and children according to the guidelines [3]. Bilateral implantation remains the minority, concerning 30% of implanted children and just 12% of implanted adults, although the number of sequential implantations is gradually increasing. Breaking down the above numbers for all bilateral implanted patients, the sequential bilateral implantation rate is greater than the simultaneous implantation rate: respectively 8% versus 4% for adults and 18%

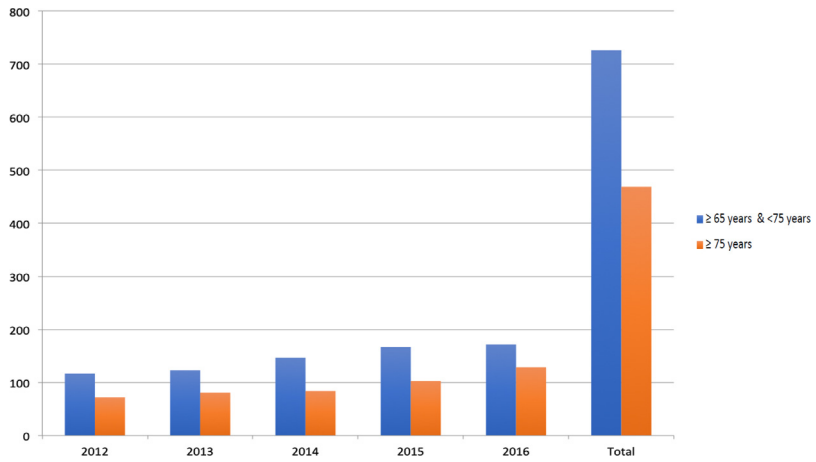

Fig. 2. Evolution of the cochlear implantations in adults over 65 years old.

versus 12% for children. In interpreting these data, it should be remembered that indications of bilateral implantation in adults are more limited than that in children.

An important aspect of the EPIIC registry is also to be able to compare the French experience with those of other European countries. In terms of bilateral implantations in children, the French rate appears to be lower than that in wider European practice (England, Belgium, Germany etc.), although the data is too scant to perform this comparison conclusively [8]. When considering all bilateral implantations, a proportional increase in sequential implantation, such as that noted in EPIIC, can also be noted in the United Kingdom between 2010 and 2012 [9]. However the definition of a sequential implementation varies between countries making the figures difficult to compare. The time-gap in bilateralization of the implantations can undoubtedly modify the clinical results and benefits obtained. In the EPIIC registry, the average delay is 18 months, but with a wide variability. If EPIIC is used as a starting point for a scientific study in the future it would be desirable for an analysis of health benefits with respect to bilateralization delay to be available.

The number of explanted patients is estimated at about 2%. This rate remains low compared to the total number of implanted patients. However, it should be noted that it is out-of-step with the cumulative survival rates reported by manufacturers. It would certainly be more accurate from a clinical point of view to report reliability according to cumulative rates of explantation [10]. Furthering the basic requirements in each country, a post-registration registry is an effective means of monitoring the occurrence of adverse events and complications, provided that the initial data is sufficiently exhaustive [4].

Monitoring implantable medical devices through a post-registration registry helps to strike a balance between essential safety and innovative technological improvements of implantable medical devices [11]. The promotion of post-registration registries, initially carried out by the main European agencies, has now become the rule with the evolution of practices in North America [12]. The monitoring of data from a post-registration registry will likely be even more relevant when it is medical, cross-referenced with other medical/administrative databases, and assisted by automatic tools that still need to be defined [13]. This point is essential to avoid underutilizing a registry and to keep the analysis pertinent [14].

The French guidelines give no upper age limit for implantation, with the caveat of severe cognitive impairment [2,3]. Even so, the percentage of subjects over 65 is very low in the study period (38% of the total number of adults implanted). This should be considered in the context of the 260,000 French over-65s estimated to have severe to profound deafness. We should surely therefore change our future National practices in view of the relationship between hearing loss and cognition that has been demonstrated by extensive epidemiological studies [14]. It should also be noted that for older subjects who have significant associated morbidity localized anesthesia may be offered if preferred [15,16].

8. Conclusion

This article reports the general indicators of the EPIIC post-registration registry. We highlight two French particularities during the period studied: a lower child bilateral implantation rate than in our neighboring European countries and a poor implantation rate in over-65 seniors: a population likely to benefit from this technique. To the best of our knowledge, the EPIIC registry is the only national registry grouping all cochlear implantation reference centers in one country.

Disclosure of interest

The authors declare that they have no competing interest.

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