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Original article

# Direct costs associated with the management of progressive early onset scoliosis: Estimations based on gold standard technique or with magnetically controlled growing rods



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## ABSTRACT

**Background:** The main disadvantage of the surgical management of early onset scoliosis (EOS) using conventional growing rods is the need for iterative surgical procedures during childhood. The emergence of an innovative device using distraction-based magnetically controlled growing rods (MCGR) provides the opportunity to avoid such surgeries and therefore to improve the patient's quality of life.

**Hypothesis:** Despite the high cost of MCGR and considering its potential impact in reducing hospital stays, the use of MCGR could reduce medical resource consumption in a long-term view in comparison to traditional growing rod (TGR).

**Materials and methods:** A cost-simulation model was constructed to assess the incremental cost between the two strategies. The cost for each strategy was estimated based on probability of medical resource consumption determined from literature search as well as data from EOS patients treated in our centre. Some medical expenses were also estimated from expert interviews. The time horizon chosen was 4 years as from first surgical implantation. Costs were calculated in the perspective of the French sickness fund (using rates from year 2013) and were discounted by an annual rate of 4%. Sensitivity analyses were conducted to test model strength to various parameters.

**Results:** With a time horizon of 4 years, the estimated direct costs of TGR and MCGR strategies were 49,067 € and 42,752 €, respectively leading to an incremental costs of 6135 € in favour of MCGR strategy. In the first case, costs were mainly represented by hospital stays expenses (83.9%) whereas in the other the cost of MCGR contributed to 59.5% of the total amount. In the univariate sensitivity analysis, the tariffs of hospital stays, the tariffs of the MCG, and the frequency of distraction surgeries were the parameters with the most important impact on incremental cost.

**Discussion:** MCGR is a recent and promising innovation in the management of severe EOS. Besides improving the quality of life, its use in the treatment of severe EOS is likely to be offset by lower costs of hospital stays.

**Level of evidence (with study design):** Level IV, economic and decision analyses, retrospective study.

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## 1. Background

Early onset scoliosis (EOS) has the potential to induce major spinal deformity, which can lead to cardio-thoracic insufficiency syndrome and result in poor prognosis if untreated [1,2]. Its management remains challenging since therapeutic approach aims at

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reducing and controlling the spinal curvature while maintaining growth of spine and thorax [3]. Until spinal fusion is indicated, the current gold standard for severe EOS management when orthopaedic management has failed is the surgical implantation of spinal growing rods. Non-fusion instrumented surgery reduces the curvature and maintains the correction by iterative distraction surgeries [4]. Although effective, EOS surgeries using traditional growing rods (TGR) can lead to several complications and affect the quality of life due to the number of surgical procedures and hospitalizations [5–7].

Some new systems have been developed to obtain a stable correction of spinal curvature while avoiding repetitive surgeries using distraction-based magnetically controlled growing rods (MCGR) [8,9].

An MCGR system was recently CE marked and is available in European countries but its use is limited as the substantial cost of this innovative device is not currently supported by Healthcare systems [10].

Despite the cost and considering the potential impact of MCGR in reducing hospital stays, we hypothesized that the use of MCGR could reduce medical resource consumption in a long-term view in comparison to TGR. Since no study reporting current costs of EOS management using TGR is available, a cost analysis was performed based on French healthcare perspective in order to evaluate whether MCGR could be cost saving compared to TGR.

## 2. Methods

The case of a young patient, presenting severe early onset scoliosis (Cobb angle superior to 45°), progressing despite optimal conservative treatment (progression of the curvature of >5° over a twelve-month period), for whom a fusionless surgery strategy, either with TGR or MCGR, is decided, was considered regardless of EOS etiology.

A cost-simulation model was constructed to compare the estimated long-term cost between TGR and MCGR with limitation to direct costs.

Cost analysis was performed in the perspective of the French National Sickness Fund. Indeed, the French health care system is characterized by its social insurance system with full support in management of severe disabling conditions such as spinal deformities. The time horizon chosen was 4 years as from the first surgical procedure. All costs were expressed in euros (€), were calculated using rates from year 2013, and were discounted by an annual rate of 4% as recommended by the French National Authority for Health's guidelines [11].

### 2.1. Medical resource expenses for TGR strategy

Medical resource expenses were estimated on the basis of data from a cohort of EOS patients treated in our centre (Hôpital Femme-Mère-Enfant, Lyon, France) with TGR between 2003 and 2010 and follow-up after index surgery – TGR implantation – for at least 12 months. Clinical data and medical expenses were retrospectively collected from those patient medical records and from the hospital information system. The mean number and duration of hospital stays, the type of instrumentation implanted, as well as the mean number of medical consultations and radiographs were considered. Eight patients (6 boys, 2 girls) with a mean age at first surgery of 5.9 ± 2.6 years were selected. All EOS were non-idiopathic with various etiologies: neurologic (38%), syndromic (38%) or congenital (25%). The mean follow-up duration from TGR implantation surgery (75% single rod/25% dual rod) to last follow-up date was 4.4 ± 2.9 years.

The expense of medical resources due to unplanned events was considered with limitation to growing rod fractures [12]. As this event did not occur in our local cohort, the associated probability was estimated based on Pubmed literature search. In case of a rod breakage, an emergency surgery was considered to repair the rod with a connector but assuming this would not modify the frequency of distraction surgeries (i.e. if a rod fracture is observed 3 months after the latest distraction surgery, a surgery would be performed but the next distraction surgery would then occur 6 months later).

At last, other medical resource consumption were estimated based on the interview of two senior paediatric orthopaedic surgeons experienced in EOS management and included:

- spinal bracing: each patient was considered to have one custom-molded orthosis every 18 months;
- physiotherapy visits: each patient was considered to have one session per week;
- medicalized transport: we considered that 50% of patients would require medical transportation after index surgery, and that 25% of patients would require transportation after distraction for an average distance of 60 km.

All the assumptions concerning medical resource expenses are reported in Table 1.

### 2.2. Medical resource expenses for MCGR strategy

The use of the MCGR system called MAGEC<sup>1</sup> was considered for this strategy. It consists of a growing rod that is magnetically drivable once implanted using a hand-held magnetic external remote controller placed on the patient's back [4] allowing non-invasive distractions. This medical device was CE marked in September 2010. We assumed its support by the French national health insurance system in addition to hospital stays. The medical resource expenses with the MAGEC system were estimated on the basis of data from the UK experience [9] which is the largest cohort reported so far (34 patients; 13 boys/21 girls; mean age at first surgery: 8 years; mean follow-up: 15 months) as well as data from our local experience on the use of this device (5 patients, 4 boys/1 girl, mean age at first surgery: 9.7 years; mean follow-up: 8 months). As for TGR, we considered an initial implantation surgery using single MCGR in 75% of cases and dual MCGR in 25% of cases plus conventional instrumentation (including screws, hooks, and connectors). After index surgery, medical expenses were medical outpatient distraction visits and full spine radiographs using EOS low dose imaging system. The capacity of MCGR to maintain spinal curvature over time after outpatient distraction visits has been described in published data up to 2 years. We considered this efficacy maintained between years of follow-up three and four on the basis of clinical experience from UK specialists.

As for TGR, the expense of medical resources due to unplanned events was considered with limitation to growing rod fractures and was estimated based on the data from the UK experience. In case of a rod breakage, an emergency surgery was considered to repair the rod with a connector adding one surgery to the management of patients.

At last, the same assumptions as the one of TGR strategy were considered for spinal bracing, physiotherapy visits, and medical transportation.

All the assumptions concerning medical resource expenses are reported in Table 1.

<sup>1</sup> Ellipse MAGEC™ Spinal System, Ellipse Technologies, DB2C France.

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