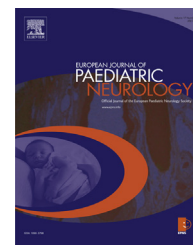




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## Original article

# Quality of life and functional outcome in early school-aged children after neonatal stroke: A prospective cohort study



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## ABSTRACT

**Background:** Quality of life (QoL) is recognized internationally as an efficient tool for evaluating health interventions. To our knowledge, QoL has not been specifically assessed in children after neonatal arterial ischemic stroke (AIS).

**Aim:** To study the QoL of early school-aged children who suffered from neonatal AIS, and QoL correlation to functional outcome.

**Method:** We conducted a multicenter prospective cohort study as part of a larger study in full-term newborns with symptomatic AIS. Participating families were sent anonymous QoL questionnaires (QUALIN). Functional outcome was measured using the Wee-FIM scale. Healthy controls in the same age range were recruited in public schools. Their primary caregivers filled in the QUALIN questionnaires anonymously. We used Student's t-test and a rank test to compare patients and controls' QoL and functional outcomes.

**Results:** 84 children with neonatal AIS were included. The control group was composed of 74 children, of which ten were later excluded due to chronic conditions. Mean ages and QUALIN median scores did not differ between patients and controls. Median Wee-FIM scores were lower in hemiplegic children than in non-hemiplegic ones ( $p < 0.001$ ). QoL scores did not seem correlated to functional outcome.

**Interpretation:** Those results could support the presence of a "disability paradox" in young children following neonatal AIS.

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## 1. Introduction

Neonatal arterial ischemic stroke (AIS) is defined as a cerebral infarction of arterial distribution diagnosed after birth and on or before the 28th day of life.<sup>1</sup> Acute neurological symptoms (seizures, hypotonia, poor feeding) in the neonatal period are the hallmark of this condition. Brain MRI is of primary importance to establishing diagnosis and prognosis.<sup>2</sup> Despite low mortality, neonatal stroke is a major cause of disability worldwide.<sup>3</sup> At least a third of children become hemiplegic, and possibly more suffer from cognitive impairment.<sup>4–6</sup> Quality of life (QoL) and health-related quality of life (HRQoL) are now internationally recognized as efficient tools for the evaluation of health interventions.<sup>7,8</sup> There is growing interest in the literature for the measurement of QoL and HRQoL in disabled children, especially in those suffering from cerebral palsy (CP).<sup>9–11</sup> Several studies in children with pediatric AIS have shown a significant impact of disease severity and impairment on HRQoL.<sup>12–14</sup> In the present study, we aimed to explore proxy-reported QoL in early school-aged children with neonatal AIS, and its correlation to functional impairment.

## 2. Patients and methods

### 2.1. Study design, setting and participants

The current study is part of a larger French multicenter prospective cohort study (the AVCnn cohort for *Accident Vasculaire Cérébral du nouveau-né*, i.e. neonatal stroke), an ongoing project initiated by the *Société Française de Neurologie Pédiatrique* in 2003. This study aims at improving knowledge on risk factors, mechanisms and determinants of outcome in a large population of neonatal AIS patients. A full description of the study protocol has been published elsewhere.<sup>3</sup>

In brief, a total of 100 full-term newborns with AIS were prospectively enrolled between November 2003 and October 2006 in 39 centers throughout mainland France. The inclusion criteria were as follows: full-term neonate presenting in the 28 first days of life with acute neurological symptoms (seizures or other paroxysmic events such as apnea, abnormal tonus or posture, altered consciousness), ischemic lesions of arterial distribution on cerebral imaging (CT and/or MRI) and parental (or legal representatives') informed consent to participate. Patients were excluded if at least one of the following criteria presented: preterm birth, absence of neonatal symptoms (accidental finding of cerebral arterial infarction or delayed neurological symptoms appearing after the 28th day of life), hypoxic-ischemic encephalopathy, multiple arterial infarcts (three or more in different territories), cerebral venous infarction, and impossibility to conduct follow-up or lack of consent. This study's cohort is now regularly followed, and families stay informed about ongoing results and future work projects by means of an annual newsletter. The present work is a prospective, ancillary cohort study conducted in France between March 2007 and April 2010. Families were contacted by phone and asked to participate. If a telephone

interview was not possible, every effort was made to contact parents by other means: regular or electronic mail, or by contacting the primary physician who took care of the affected child.

For the families who agreed orally to participate, a QoL questionnaire was sent by regular mail, and returned in the same way. Functional outcome was measured by telephone using the French version of the Wee-FIM scale. The interviews were conducted by a trained investigator who was masked to children's clinical status (CR). For each patient, assessment was conducted at 3.5 years of age.

During the same period, a control group was recruited in public schools of the Rhône-Alpes region, France, from classes called "*petite section de maternelle*" and grouping young children from 3 to 4 years of age. The same QoL questionnaires were anonymously filled by each child's primary caregivers. Other data collected were age and the presence of a chronic condition or disability.

### 2.2. Outcome measurements, studied variables and definitions

We used a generic QoL questionnaire: the QUALIN (*Qualité de vie du nourrisson et du jeune enfant*) questionnaire. It is a 34-item, proxy-reported scale, designed for pre or early school-aged children, and validated on a European population of 705 children aged 3 months to 3 years.<sup>15</sup> The French version has been translated into English (Fig. 1), Italian and Spanish and has shown good psychometric properties (90% acceptability, Cronbach's alpha coefficient over 0.75, inter-rater reliability over 0.5 and a good construct validity). For each item, subscores are expressed as a five-point Likert scale (from –2 "definitely false" to +2 "definitely true"). Negative items (items n° 4,6,10,14,17,20,27 and 30) are reverse-scored (from –2 "definitely true" to +2 "definitely false"). Between 1 and 3 years of age, items are grouped into four major dimensions: psychomotor development (items n° 3,5,8,13,16,18,21,22,24,32 and 33), psychological and physical well-being (items n° 1,2,4,6,12,14,20,27,28 and 30), sociability (items n° 9,19,25 and 34) and family environment (items n° 11,26,29 and 31). Items not included in any of those dimensions are items n° 7,10,15,17 and 23. Mean completion time is 10 min. The Wee-FIM scale is the paediatric version of the Functional Independence Measure scale. It was validated in a population of healthy American children, and later in 167 French children aged 6 months to 7 years.<sup>16,17</sup> This scale is used to clinically assess children's functional independence, and comprises 18 items scaled from 1 to 7, with the subscore normally increasing with age. The total score varies between 18 (minimal independence) and 126. Mean completion time is 15–30 min with a trained observer. The scale can be completed by phone via proxy-report.<sup>18</sup> It has shown good accuracy and reproducibility.<sup>16</sup> Furthermore, in the 3–4 years age range, mean scores are similar between French and American children.<sup>17</sup>

As children were previously assessed for motor outcome at 2 years of age, they were also classified as having or not cerebral palsy (CP), which was unilateral and spastic (hemiplegic) in all cases (see Husson et al., 2010 for more details).<sup>2</sup>

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