

Severe sialorrhea: patient journey and related costs reveal unmet medical needs

Context

Severe sialorrhea can be observed in up to 60% of children with chronic neurological disorders¹. This symptom of severe drooling largely impacts the patient's quality of life. As of today, very little information is available on the management of patients with severe sialorrhea and the related costs.

Objectives

- Better understand the care pathway of patients with severe sialorrhea in France
- Estimate the costs related to the management of this condition

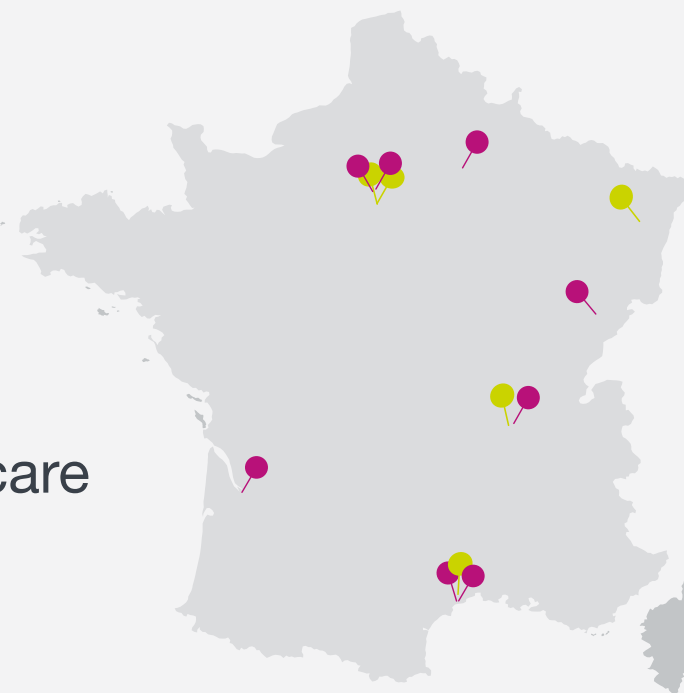
Methods

Qualitative interviews

Conducted with 10 healthcare professionals (HCP), including 5 pediatric neurologists and 5 ear, nose and throat (ENT) specialists.

Data collection on patient cases

Data on 50 patient cases were collected nationwide through 14 HCP (8 pediatric neurologists and 5 ENT specialists). To be included, patients had to be aged between 5 and 18 years old and currently followed by an HCP for severe sialorrhea. HCP had to fill in a detailed questionnaire for each patient case including patient's sociodemographic information, healthcare pathways, and treatment received.



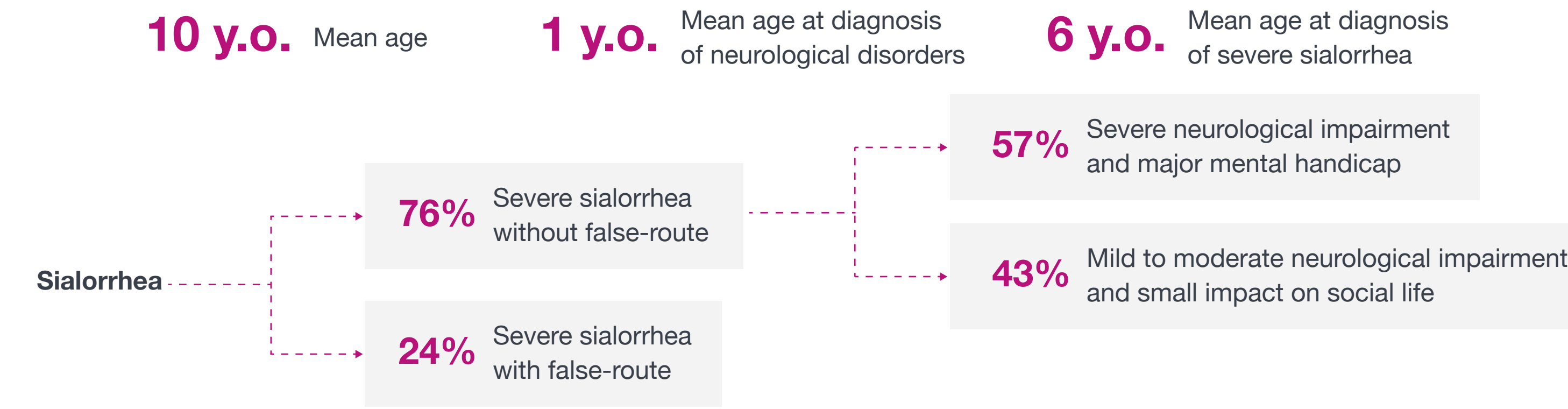
Costs

Estimated using French medico-economic data available in open access including "diagnosis-related group" costs, medicine costs, as well as posology and duration of treatment.

Conclusion

This study highlights that no ideal therapies exist for the management of severe sialorrhea: there is a clear need for specific medications approved for this indication. Having reimbursed therapeutic option would also support patient and families to deal with this condition in the future.

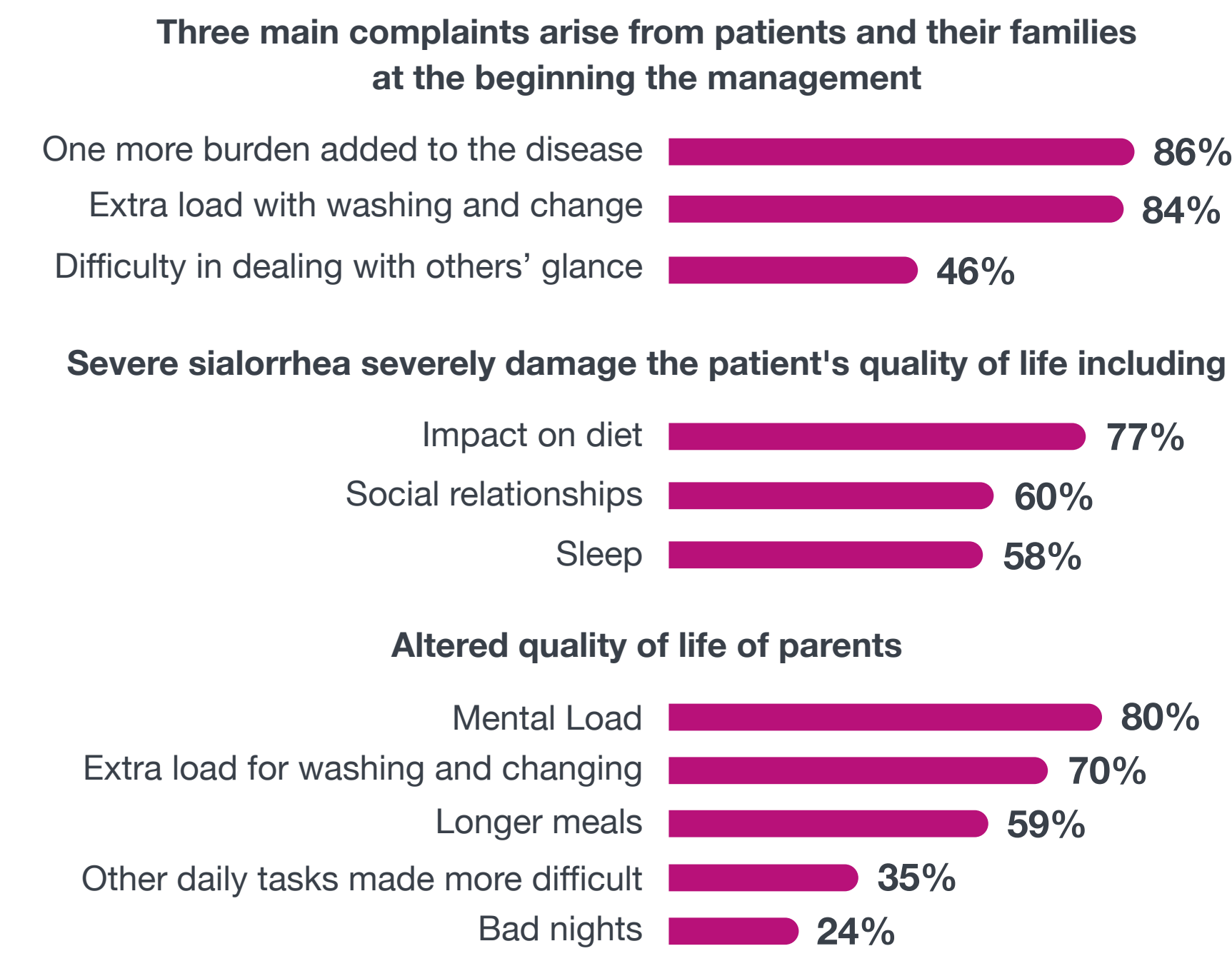
Profiles of patient with severe sialorrhea, N=50



→ Diagnosis of the neurological disorder is made at 1 year of age, whereas sialorrhea is diagnosed much later, at a mean age of 6 years. 2 main patient profiles can be described according to the severity of sialorrhea.

4 main steps in the healthcare pathways

1 BURDEN BEFORE DIAGNOSIS/TREATMENT



→ A diagnosis most often made by the pediatric neurologist who follows the child for the chronic neurological disorder. Sialorrhea is identified visually and evaluated in a follow-up consultation as part of the child's overall assessment. Severe sialorrhea has a strong impact on patient's quality of life.

2 BEGINING OF CARE MANAGEMENT

Care can be triggered in case of :

- Morbid repercussions (weight loss, increase in seizures or convulsions, pulmonary infections).
- Hospitalizations, for more severe cases, imply a direct entry to step 3 (29% of the 50 patient cases have been hospitalized for a reason related to severe sialorrhea).
- Request for help from parents due to heavy consequences on the quality of life.

→ Paramedics are usually involved first but rarely specialized for the management of this condition and their involvement is rarely sufficient for the stabilization of severe sialorrhea.

Results

Profiles of healthcare professionals involved

- Pediatric neurologists**
Referral physicians for these patients, intervening on all aspects inherent to their disease and, therefore, essential in the management of severe sialorrhea.
- ENT specialists**
A broad specialty, an unattractive disease and complex patients, ENT specialists not always oriented toward severe sialorrhea and levels of involvement vary.
- Pulmonologists**
Emergency intervention in serious situations related to complications of the most severe forms of sialorrhea.
- Radiologists / Anesthetists**
Involved for botulinic injections.

→ In addition, paramedics, such as dieticians, physiotherapists, psychometricians and speech therapists, are involved early in the care management.

3 PATIENT MANAGEMENT AND TREATMENT

	Scopolamine patches	Botulinic toxin injections	Trihexyphenidyl	Atropine collyrium
Pourcentage of used	64%	34%	26%	4%
by line: line 1 line 2 line 3	48% 16%	14% 14% 6%	24% 2%	
Type of treatment	Patches (can be folded to adjust posology delivered)	Injections requiring hospitalisations	Antiparkinsonian treatment, oral solution (drops)	Atropine collyrium used ingested
Prescribers	Can be recommended by neurologists or ENT specialists	Mainly prescribed by ENT specialists	Can be prescribed by neurologists only in France	Can be recommended by neurologists or ENT specialists
Cost per therapy per year including administration cost	921.60�	6,532.10� 6,222.14�	6.29�	1828.01�
Advantages & difficulties observed in real-life				
Reimbursed by the French social insurance	� No	� Hospital management paid by social insurance	� Yes	� Used as a substitute of the non-reimbursed patch
Administration	� Dosing management can be challenging : necessity to fold or to cut patches to adjust the dose	� Injections are invasive and require local or most of the time general anesthesia	� Can be used even in the younger patients	• Can be used even in the younger patients • No adequate drug formulation
Efficacy	• Neurologists usually satisfied with the efficacy observed • High early discontinuation rate (56%), often related to insufficient efficacy (60%) or high cost (40%)	• Good solution, often effective • Considering the limited duration of the efficacy, re-injections need to be considered up to 3 times per year	� Limited efficacy observed (declared by 89% patients treated with Artane)	� No clear dosage guidance exists
Tolerance	� Adverse events observed such as increase of seizures, dry mucous membranes	� Overall well tolerated	� No complaints reported within this study regarding the tolerance	� Ocular and urinary adverse events to monitor
Approved use for severe sialorrhea	� Off-label use	� Yes	� Off-label use	� Off-label use

→ Different treatments suggested depending on the physician consulted. Four main therapeutical options were identified by the HCP interviewed, but no treatment is unanimously accepted. In total, still about 10% of the patients remain without treatment because not taken or early stopped.

4 LASTING RELIEF AND DISORDER DISAPPEARANCE

5 years

Of follow-up for patients with severe sialorrhea in average

→ Practitioners interviewed agree on the fact that severe sialorrhea usually fades away around 14 years-old.

When patients become adults, practitioners note that very few patients remain symptomatic, and these rare cases are usually transferred to an adult neurologic service.