

HEALTH, SOCIAL AND FINANCIAL IMPACT OF PROVIDING ACCESS FOR ACUTE STROKE PATIENTS TO INTEGRATED STROKE CARE CENTRES. COST-UTILITY STUDY ASSOCIATED WITH THE RACECAT TRIAL

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1. Project Summary

Objectives

In patients with suspected ischemic stroke due to occlusion of a large vessel located in a geographical area where the reference center is a local stroke center (transport time to tertiary center with endovascular treatment capacity is greater than transport time at the local stroke center):to evaluate the cost-effectiveness of the direct transport strategy to the tertiary center (mothership) with respect to transport to the local center and then to the tertiary center in case of need for endovascular treatment (drip-andship) (Figure 1).



Figure 1. Diagram of the two transfer circuits compared in the RACECAT study

Specifically:

- To assess survival and quality-adjusted survival (QALY) of both alternatives.

- To estimate the costs of health care in the acute and subacute phase and up to one year after the initial admission.

- To estimate the incremental cost-effectiveness and cost-utility ratio under the Health System perspective.

Secondary goals:

- To assess the impact of the mothership vs drip-and-ship strategy on one-year survival, degree of disability and quality of life

- To provide descriptive information about the costs in the different categories that may be relevant to decide the future organization of acute stroke care from a social perspective.

- To assess the impact of stroke on the loss of productivity of "informal" patients and caregivers and the burden and quality of life of caregivers

Methodology

This is a cost-effectiveness study in parallel with the RACECAT multicenter randomized clinical trial under current clinical practice.

The study is based on different data sources:

 Data collected prospectively within the clinical trial: Baseline characteristics of patients, comorbidities and severity and subtype of stroke. Reperfusion therapy.
Adverse events and outcome (modified Rankin scale, mRS) at 3 months. Time between onset of symptoms, alert to emergency systems, arrival of emergency systems, neuroimaging test, puncture and end of treatment. Data on the care of emergency systems, types of transport and geolocation.

- Data collected retrospectively from administrative databases and medical history: use of resources during hospitalization and follow-up. Mortality, acute hospitalizations, long stay, rehabilitation, medical visits, pharmacological treatment.

- Data collected through a centralized telephone interview with patients and caregivers at 3, 6 and 12 months of stroke: socio-demographic, functional capacity and disability (Barthel and mRS), quality of life (EQ5D5L), need for formal caregiver or informal, loss of patient and caregiver productivity, need for physical adaptations at home

The data are analyzed primarily from the perspective of the Catalan Health Service but also, given the importance of the social perspective, secondary analyses will be made including the loss of productivity of patients and caregivers and other expenses not faced by the public system. Data is analyzed over a one-year time horizon and the result will also be modeled over a time horizon until the end of life.

QALYs are estimated based on survival and utilities calculated using the EQ5D5L Generic Quality of Life Questionnaire.

Costs are estimated using different methods: analytical accounting in a hospital at each level for the acute and subacute phase, and billing costs or costs for the consumption of health resources during follow-up. Informal caregiver costs are estimated using cost- opportunity and/or proxy good methods.

2. Results obtained

A total of 629 patients who had been included in the RACECAT clinical trial consecutively between September 2017 and January 2019 were included in the cost-effectiveness sub-study (Figure 2). Of these, 451 surviving patients participated in follow-up interviews at 3 months, 372 at 6 months, and 350 at 12 months, with a total follow-up loss of 3.8%.



Figure 2. Flow of patients included in the study and patients followed.

Table 1 presents the characteristics of the patients included in the study. They have similar characteristics in terms of pathological history and the type and severity of the

stroke but, as expected in the group of direct transfer to the endovascular center, there was a higher proportion of patients receiving endovascular treatment.

	Total N=629	EVT-SC N=316	Local-SC N=313	p-value
Age, m (SD)	73.47 (13)	74.5 (12)	72.4 (14)	0.045
Female, n(%)	272 (43%)	126 (40)	146 (47)	0.087
Diagnosis				0.533
Ischemic LVO	303 (48)	162 (51)	141 (45)	
Ischemic no LVO	134 (21)	64 (20)	70 (22)	
Hemorrhagic	136 (22)	74 (24)	62 (20)	
Stroke mimic	42 (7)	22 (7)	20 (6)	
Transient ischemic accident	14 (2)	8 (2)	8 (3)	
RACE 8-9	213 (34)	106 (34)	107 (24)	0.865
History:				
Hypertension	451 (72)	233 (73)	218 (70)	0.255
Dyslipemia	301 (48)	163 (52)	138 (44)	0.060
Smokers	89 (14)	41 (13)	48 (15)	0.396
Alcohol abuse	43 (7)	20 (6)	23 (7)	0.613
Diabetes	164 (26)	100 (32)	64 (20)	0.001
Cardiopathy	78 (12)	48 (16)	30 (10)	0.033
Heart failure	58 (9)	33 (10)	25 (8)	0.287
Peripheral arterial disease	26 (4)	17 (5)	9 (3)	0.115
Stroke or TIA	93 (15)	56 (18)	37 (12)	0.037
Atrial fibrillation	179 (28)	94 (30)	85 (27)	0.472
Anticoagulation	127 (20)	70 (22)	57 (18)	0.218
Treatment received (n=437 ischemic):				
None	120 (27)	57 (25)	63 (30)	0,001
Endovascular	77 (18)	56 (25)	21 (10)	
rtPA	119 (27)	54 (24)	65 (31)	
Both	121 (28)	59 (26)	62 (29)	
Total endovascular	198 (45)	115 (51)	83 (39)	0,008
Neurosurgical intervention	22 (3.5)	11 (3.5)	11 (3.5)	0.982

Table 1. Clinical characteristics of the included patients

Survival in both groups was also similar (Figure 3) as was the evolution of the functional status (Figure 4) at 6 and 12 months. We can therefore say that the clinical impact of stroke was equivalent in both treatment groups. This translates into a similar need for health resources (visits to primary care, hospitalizations in acute or socio-

health hospital, home care, drug use) and social (formal or informal caregiver hours, home adaptation needs) in the 12 months' time window.



Figure 3. Survival by randomization group



Figure 4. 6 and 12 months mRS

If we translate the consumption of resources into costs we see that the cost is also similar in both groups (Figure 5A). The largest proportion of the total cost (close to $\leq 15,000$ per patient in the 12-month post-stroke period) is due to hospital care, including the acute phase and the need for new hospitalizations in acute care or sociosanitary during follow-up. However, a large part of the cost (around $\leq 10,000$ per patient in a 12-month period) corresponds to the hours of the caregiver ("informal" or formal).

If we distribute the costs according to mRS (Figure 5.B) we see that the cost increases considerably depending on the level of dependence.



Figure 5. Costs by randomization group and by mRS scale

3. Relevance and possible future implications

First, findings of this study may have implications for the design of prehospital systems of care for acute stroke. Because direct transport to a thrombectomy-capable center was found to be as efficient as initial transport to local stroke-centers, the best transport paradigm involving patients with suspected acute stroke due to LVO may be defined by local factors such as achievable workflow metrics, established practice patterns, and availability of local resources, rather than following a "one size fits all" approach.

Second, the study shows that the greatest health expenditure after a stroke is mainly due to hospitalization in the acute phase and the need for admission to socio-health centers during the first months after the stroke. In addition, the cost associated with the need for care represents half of the total cost in patients with moderate to severe disability. This fact highlights the need and importance of evaluating the impact of stroke also from a social perspective.

The optimization of stroke treatment in the acute phase is progressively improving the chances of survival, but unfortunately it also increases the number of people who survive with sequelae and the consequent need for health and social care. This strong impact highlights the need for investment not only in stroke prevention and the organization of the acute phase but also in integrated care (health and social care) for patients and their families.

The study also shows an important impact on home care needs, which are basically covered by relatives who act as "informal" caregivers. This is a growing problem in our society, generating a constantly growing variety of new economic activities focused on the provision of services to the elderly or people with disabilities. Detailed description of the costs associated with the care of people with disabilities can be useful for the design of new policies aimed at mitigating this problem and promoting equity in access to these services.

4. Generated Scientific Bibliography

The project has not yet generated scientific literature. The results of the main RACECAT study have been published very recently, opening the door to future publications generated by this sub-study. There are currently three articles in preparation that will most likely be published soon in high-impact indexed journals. Provisional titles of these three works are:

1. Cost-effectiveness of direct transport of stroke patients with suspected large vessel occlusion to a tertiary center with thrombectomy availability

2. Impact of stroke sequelae on the consumption of health and social resources and costs

3. Impact of stroke disability on the burden, quality of life and job losses of "informal" caregivers. Gender differences