



Current territorial organization for access to revascularization therapies for acute ischemic stroke in the Veneto region (Italy) from 2017 to 2021

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Abstract

Introduction To evaluate the access to treatments with intravenous thrombolysis (IVT) and/or mechanical thrombectomy (MT) in acute ischemic stroke patients admitted to stroke units (SUs) of Veneto region (Italy) according to current “hub-and-spoke” model from 2017 to 2021.

Patients and methods We retrospectively analyzed data on treatments with IVT and/or MT for stroke patients admitted to the 23 SUs (6 Hubs and 17 Spokes) of the 6 macro-areas including 9 local sanitary units (LSUs) and 2 hospitals.

Results We reported 6093 treatments with IVT alone, 1114 with IVT plus MT, and 921 with MT alone. Number of stroke unit (SU) beds/100,000 inhabitants ranges from 2.3 to 2.8, and no difference was found among different macro-areas. Number of treatments/100,000 inhabitants/year ranges from 19 to 34 for IVT alone, from 2 to 7 for IVT plus MT, and from 2 to 5 for MT alone. Number of IVT alone/SU bed/year ranges from 9 to 21 in the Hub and from 6 to 12 in the Spokes. Rate of IVT plus MT in patients directly arrived in the same LSU’s Hub ranges from 50 to 81%, likewise the one of MT alone ranges from 49 to 84%.

Conclusions Treatment target rates of IVT and MT set by Action Plan for Stroke in Europe 2018–2030 has been globally exceeded in the Veneto region. However, the target rate of MT and access revascularization treatments is heterogeneous among different macro-areas. Further efforts should be made to homogenize the current territorial organization.

Keywords Thrombolysis · Thrombectomy · Stroke · Hub-and-spoke model

Introduction

A survey conducted by Aguiar de Sousa et al. on intravenous thrombolysis (IVT) and endovascular treatment (EVT) in 44 European countries has observed major inequalities in acute stroke treatment between and within countries [1]. The survey has involved 1.5 stroke units (SUs) per 1000 annual incident ischemic strokes, nevertheless individual country-level data indicate that access to acute stroke care are insufficient, and differences inter/intra-country are considerable. Less than 20% of patients

with acute ischemic stroke had access to IVT treatment, while the IVT overall treatment rate in incident ischemic stroke was 7.3%. EVT was performed in only 0.4 centers per 1000 annual incident ischemic strokes, whereas only 1.9% of all acute ischemic stroke patients have received the treatment. Based on previous data revealing that the access to revascularization therapies for acute ischemic stroke was restricted in several macro-areas, the European Stroke Organization (ESO) prepared a European Stroke Action Plan for the years 2018 to 2030 and set treatment target rates for all European countries [2].

We aimed to evaluate the access to treatments with IVT and/or mechanical thrombectomy (MT) in acute ischemic stroke patients admitted to the SUs of Veneto region (Italy) according to current “hub-and-spoke” model during a period of 5 years.

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Methods

Study design, participants, and procedures

We retrospectively analyzed prospectively collected data on acute revascularization treatments in ischemic stroke patients admitted at the SUs of Veneto region in Italy during a period of 5 years from January 1, 2017 to December 31, 2021.

After defining the criteria for identifying the centers suitable for practicing IVT and the identification of specialized hospital centers authorized to use Alteplase for the treatment of acute ischemic stroke in the context of the SIST-MOST study (Veneto region deliberation DGR 1363 dated 07/mag/2004), stroke network has been established in the Veneto region at the end of 2008 according to a “hub-and-spoke” model (Veneto region deliberation DGR 4198 dated 30/dic/2008). The “hub-and-spoke” model included 6 Hubs (Mestre, Padova, Rovigo, Treviso, Verona, and Vicenza) and 17 Spokes (Arzignano, Bassano del Grappa, Belluno, Castelfranco Veneto, Cittadella, Feltre, Conegliano Veneto, Legnago, Mirano, Negrar, Padova Sant’Antonio, Peschiera del Garda, Piove di Sacco, Portogruaro, Santorso, Schiavonia/Monselice, and Venezia) (Supplemental Fig. 1). Spokes can perform IVT, while Hubs can perform both IVT and MT. According to the “hub-and-spoke stroke network”, patients admitted to a Spoke received IVT and were transferred to reference Hub to receive MT when they were eligible.

From January 1, 2017, the geographical area of the Veneto region — a geographical area of 4,915,751 inhabitants — is divided into the following 9 local sanitary units (LSUs, public authorities of the Italian public administration, responsible for the provision of health services in a specific territory): LSU-1 “Dolomiti” (206,795 inhabitants), LSU-2 “Marca Trevigiana” (885,349 inhabitants), LSU-3 “Serenissima” (640,399 inhabitants), LSU-4 “Veneto Orientale” (215,391 inhabitants), LSU-5 “Polesana” (243,212 inhabitants), LSU-6 “Euganea” (934,659 inhabitants), LSU-7 “Pedemontana” (367,961 inhabitants), LSU-8 “Berica” (499,430 inhabitants), and LSU-9 “Scaligera” (922,555 inhabitants) (Veneto region law n. 19 dated 25/ott/2016) (Supplemental Fig. 2). The geographical area of the Veneto region includes also the Azienda Ospedaliera Padova (AO-PD) and the Azienda Ospedaliera Universitaria Integrata Verona (AOUI-VR).

According to the “hub-and-spoke” model for stroke on the mapping of LSUs, six macro-areas are identified as follows: LSU-1 combined with LSU-2 (Treviso SU as Hub), LSU-3 combined with LSU-4 (Mestre SU as Hub), LSU-6 combined with AO-PD (Hub), LSU-7 combined with LSU-8 (Vicenza SU as Hub), and LSU-9 combined with AOUI-VR (Hub). LSU-5 is not combined (Rovigo SU as Hub). Stroke patients arrived at Rovigo (Hub) received MT during the day-time hours on weekdays and were referred to AO-PD (Hub)

to perform MT during the night hours on weekdays and on holidays. CT angiography (CTA) was performed systematically at admission in stroke patients arrived at AOUI VR (Hub), Peschiera del Garda, Legnago, Arzignano, Bassano del Grappa, Belluno, and Mirano, whereas CTA was performed at admission in patients arrived at other Hubs and Spokes who had NIHSS score ≥ 6 , ASPECT score ≥ 6 , and pre-stroke mRS < 2 or < 3 . CTA was performed at admission in stroke patients arrived at Feltre and Mirano during the day-time hours. LSU-7 and LSU-8 and have been equipped with automated computed tomography image (CTI) analysis software in the last year of study (2021).

Data collection

Data on number of IVT alone, IVT plus MT, and MT alone per year for each SU were collected by annual report of the regional coordinator of the Italian Stroke Association (ISA). Number of SU beds for each SU and criteria for CTA use and availability were recorded by the regional coordinator of the ISA. From 2009 to 2016, only data on the total number of IVTs per year in Hubs and Spokes were recorded. Total number of ischemic strokes among residents of Veneto region from 2017 to 2020 was collected according to administrative flows (DRG system, ICD code: (433.01, 433.11, 433.21, 433.31, 433.81, 433.91, 434.01, 434.11, 434.91, and 436). Data on total number of ischemic strokes among residents of Veneto region in 2021 were not available.

Outcome measures

For each macro-area, we calculated the following outcome measures for IVT alone and total IVT: (1) number of treatments/100,000 inhabitants/year; (2) number of treatments in the Hub/SU bed/year; (3) number of treatments in the Spoke/SU bed/year. In addition, we calculated the following outcomes for IVT plus MT, MT alone, and total MT: (1) number of treatments in patients of the same macro-area/100,000 inhabitants/year; (2) number (%) of treatments in patients directly arrived at Hub of the same macro-area/total number of treatments in patients of the same macro-area; (3) number (%) of treatments in patients referred to another macro-area/total number of treatments; and (4) number (%) of treatments in patients arrived from another macro-area/total number of treatments.

Statistical analysis

We performed statistical analyses using SPSS 22.0 statistical package and STATA-16 software. Proportions were calculated for categorical variables, dividing the number of events

by the total number. Categorical variables were expressed as frequency and percentage. The best macro-area was identified as reference for each outcome measure. Each macro-area was compared with the reference using χ^2 test.

Results

During a period of 5 years (2017–2021), we reported 6093 treatments with IVT alone, 1114 treatments with IVT plus MT, and 921 treatments with MT alone for ischemic stroke in the six macro-areas of Veneto region.

The number of treatments per year in LSU-1 and LSU-2 (Supplemental Table 1), LSU-3, and LSU-4 (Supplemental Table 2), LSU-5 (Supplemental Table 3), LSU-6 and AO-PD (Supplemental Table 4), LSU-7 and LSU-8 (Supplemental Table 5), LSU-9 and AOUI-VR (Supplemental Table 6) are provided in the online-only Data Supplement.

Comparison of outcome measures among different macro-areas in IVT plus MT, and MT alone are reported in Table 1. No difference was found between LSU-5 (Reference: 2.8 SU beds) and other macro-areas on number of SU beds/100,000 inhabitants.

Regarding IVT alone, the number of treatments/100,000 inhabitants/year was lower in LSU-3/LSU-4 ($n=19$), compared with those carried out by LSU-9/AOUI-VR ($n=34$). The number of treatments in the Hub/SU bed/year was lower in LSU-1/LSU-2 ($n=10$; $p=0.048$), in LSU-5 ($n=9$; $p=0.028$), and in LSU-7/LSU-8 ($n=10$; $p=0.048$), compared with the one processed by LSU-9/AOUI-VR ($n=21$; reference). No difference was found for number of treatments in the Spoke/SU bed/year between LSU-1 and LSU-2 ($n=12$ treatments; reference) and other macro-areas.

About IVT plus MT, no difference was found for number of treatments in patients of the same macro-area/100,000 inhabitants/year between LSU-5 ($n=7$; reference) and other macro-areas. The number (%) of treatments in patients directly arrived in the Hub of the same macro-area/total number of treatments in patients of the same macro-area was lower in LSU-1/LSU-2 ($n=70$, 52%; $p<0.001$), in LSU-3/LSU-4 ($n=86$, 50%; $p<0.001$), in LSU-6/AO-PD ($n=112$, 52%; $p<0.001$), and in LSU-7/LSU-8 ($n=119$, 59%; $p<0.001$), compared with LSU-9/AOUI-VR ($n=220$ treatments, 81%; reference).

Regarding MT alone, no difference was found for number of treatments in patients of the same macro-area/100,000 inhabitants/year between LSU-6/AO-PD ($n=7$) and other macro-areas. number (%) of treatments in patients directly arrived at the Hub of the same macro-area was lower in LSU-3/LSU-4 ($n=120$, 66%; $p<0.001$), in LSU-6/AO-PD ($n=158$, 62%, $p<0.001$), in LSU-7/LSU-8 ($n=86$, 49%, $p<0.001$), compared with LSU-9/AOUI-VR ($n=134$ treatments, 84%; reference).

Comparison of outcome measures among different macro-areas in total IVT and total MT (Supplemental Table 7) are provided in the online-only Data Supplement.

Total number of IVT per year in Hubs vs Spokes from 2009 to 2016 were the following: 192 vs 77 in 2009, 211 vs 146 in 2010, 266 vs 235 in 2011, 344 vs 231 in 2012, 407 vs 274 in 2013, 484 vs 465 in 2014, 564 vs 502 in 2015, and 667 vs 617 in 2016.

Total number of ischemic strokes among residents of Veneto region from 2017 to 2020 was 6975 (142 per 100,000 inhabitants), in 2017, 6870 (140 per 100,000 inhabitants) in 2018, 6842 (139 per 100,000 inhabitants) in 2019, and 6344 (129 per 100,000 inhabitants) in 2020. Total number (%) of IVT alone on total number of ischemic strokes among residents of Veneto region was 1228 (17.6%) in 2017, 1281 (18.6%) in 2018, 1302 (19%) in 2019, 1143 (18%) in 2020, 1139 in 2021. Total number (%) of IVT plus MT on total number of ischemic strokes among residents of Veneto region was 170 (2.4%) in 2017, 212 (3.1%) in 2018, 241 (3.5%) in 2019, 241 (3.8%) in 2020, and 250 in 2021. Total number (%) of MT alone on total number of ischemic strokes among residents of Veneto region was 96 (1.4%) in 2017, 145 (2.1%) in 2018, 177 (2.6%) in 2019, 202 (3.2%) in 2020, and 301 in 2021.

Discussion

This study reports the number of treatments per 100,000 inhabitants annually performed in Veneto region (Italy) between 2017 and 2021, which ranged from 19 to 34 for IVT alone, from 2 to 7 for IVT plus MT and from 2 to 5 for MT alone in the different macro-areas. The global rate of IVT on total number of ischemic strokes among residents of Veneto region between 2017 and 2020 was more than 20%, while the global rate of MT exceeded 5% in 2018, reaching 7% in 2020. Our data shows that the number of treatments has grown progressively over the years and the treatment target rate of IVT and MT (i.e., the total number of treatments divided by the total number of patients with ischemic stroke and multiplied by 100) set by Action Plan for Stroke in Europe 2018–2030 [2], respectively at 15 and 5%, has been globally exceeded in Veneto region. However, our data show that the access to revascularization therapies is heterogeneous among different macro-areas, as reported by previous survey in 44 European countries [1].

Our study reports that the annual number of treatments per SU bed performed in the Hub ranges from 9 to 21 for IVT alone, while the one carried out for IVT alone per SU bed annually in the Spokes ranges from 6 to 12. These results have detected despite the number of SU beds per 100,000 inhabitants — from 2.3 to 2.8 SU beds per 100,000 inhabitants — is similar among different macro-areas. Only in one macro-area, the number of treatments per SU bed

Table 1 Comparison of outcome measures among different macro-areas in IVT plus MT, and MT alone

	LSU-1 Dolomiti, LSU.2 Marca Trevigiana		LSU-3 Serenissima, LSU-4 Veneto Orientale		LSU-5 Polesana		LSU-6 Euganea, AO-PD		LSU-7 Pedemontana, LSU-8 Berica		LSU-9 Scalligera AOUI-VR	
	Treviso—Hub	P value	Mestre—Hub	P value	Rovigo—Hub	P value	AO-PD—Hub	P value	Vicenza—Hub	P value	AOUI-VR—HUB	P value
SU beds/100,000 inhabitants/year	2.5	1.000	2.3	1.000	2.8	Reference	2.4	1.000	2.5	1.000	2.4	1.000
IVT alone												
Treatments/100,000 inhabitants/year	21	0.080	19	0.039*	27	0.370	23	0.145	26	0.302	34	Reference
Treatments in the Hub/SU bed/year	10	0.048*	18	0.631	9	0.028*	20	0.876	10	0.048*	21	Reference
Treatments in the Spoke/SU bed/year	12	Reference	6	0.157	0	NA**	8	0.371	10	0.670	10	0.670
IVT plus MT												
Treatments in patients of the same macro-area/100,000 inhabitants/year	2	0.096	4	0.366	7	Reference	5	0.564	5	0.564	6	0.782
Treatments in patients directly arrived at Hub of the same macro-area/Total treatments in patients of the same macro-area (%)	70 (52%)	<0.001*	86 (50%)	<0.001*	54 (100%)	NA**	112 (52%)	<0.001*	119 (59%)	<0.001*	220 (81%)	Reference
Treatments in patients referred to another macro-area/total treatments (%)	3 (2%)	<0.001*	1 (<1%)	<0.001*	34 (39%)	Reference	1 (<1%)	<0.001*	5 (2%)	<0.001*	0	<0.001*
Treatments in patients arrived from another macro-area/total treatments (%)	1 (<1%)	<0.001*	2 (1%)	<0.001*	0	<0.001*	36 (14%)	Reference 2 (1%)	Reference 2 (1%)	<0.001*	1 (<1%)	<0.001*
MT alone												
Treatments in patients of the same macro-area/100,000 inhabitants/year	2	0.257	4	0.739	4	0.739	5	Reference 4	Reference 4	0.739	3	0.480
Treatments in patients directly arrived at Hub of the same macro-area/total treatments in patients of the same macro-area (%)	74 (78%)	0.201	120 (66%)	<0.001*	33 (100%)	NA**	158 (62%)	<0.001*	86 (49%)	<0.001*	134 (84%)	Reference
Treatments in patients referred to another macro-area/total treatments (%)	0	<0.001*	1 (<1%)	<0.001*	20 (38%)	Reference	0	<0.001*	0	<0.001*	0	<0.001*
Treatments in patients arrived from another macro-area/total treatments (%)	1 (1%)	0.028*	0	<0.001*	0	<0.001*	19 (7%)	Reference 1 (<1%)	Reference 1 (<1%)	0.001*	0	<0.001*

* Significance, ** LSU 5 Polesana includes only Rovigo SU as Hub

annually was lower in the Hub than in the Spokes (10 versus 12). The disparity of IVT use related to different geographic areas, volume centers, and levels of health care has already been reported [3].

Our study reports that rate of treatments with IVT plus MT ranges from 50 to 81% in patients directly arrived at the Hub of the same macro-area; similarly, rate of treatments with MT alone ranges from 49 to 84% in patients directly arrived at the Hub of the same macro-area. The transfer of patients from one macro-area to another to perform MT has almost never occurred, and was made only by Rovigo Hub of the LSU-5 that has benefited from the major capacity of AO-PD Hub of the LSU-6 for MT during the 12-night hours of weekdays and holidays. Our data confirm a previous our study enrolling 512 consecutive ischemic stroke patients who received IVT and/or MT, from September 17 to December 9, 2018, in 25 SUs in Triveneto, a geographical macro-area in Northeast of Italy. Previous study shows a net reduction of patients transferred from a Spoke to a Hub to receive MT, compared with those patients who are directly admitted to a Hub [4]. In line with the previous observations on “drip-and-ship” model [5], our study has also reported how onset-to-door time was shorter in the Spokes, while door-to-needle time and needle-to-groin puncture time were shorter in the Hubs. Our data are also consistent with a comprehensive population-wide data from 11 US states with 80 million residents showing that less than 50% of patients with ischemic stroke initially received care at facilities capable of MT [6]. Non-urban patients were less likely to initially receive care at the Hubs than residents of urban cores, and rural patients were particularly likely to present to thrombectomy gaps that did not offer transfer to a thrombectomy-capable hospital.

Our study has some limitations. First, data on the number of ischemic stroke patients admitted to each SU per year was not available. Second, we are unable to exclude if the number of SU beds was reduced sometime during the observation period, especially in the Spokes. Third, we are unable to identify possible differences and changes during the observation period regarding health personnel for stroke patients among macro-areas, especially in the Spokes. These limitations mainly concern the period of the COVID-19 pandemic, especially the first wave of the pandemic. However, the observation period of the study is long and also includes the previous non-COVID-19 phase. Finally, we are unable to quantify how geographical differences of the local territory can affect the access to revascularization therapies for ischemic stroke among macro-areas, especially in the rural area.

Despite these limitations, the present study is the first report to assess the efficiency of the “hub-and-spoke” model in stroke patients who received IVT and/or MT in the real life setting of an Italian region during a period of 5 years.

Acute stroke care in hospitals is best performed in SUs, which are the essential part of the chain of recovery and form the backbone of pre-hospital, in-hospital, and post-hospital care. Nevertheless, the number of all stroke patients who are not treated in an SU as the first level remains in some regions of Europe still well below the target set by Action Plan for Stroke in Europe 2018–2030 (i.e., $\geq 90\%$). Future studies will be needed to verify if the target is achieved in the Veneto region. However, based on similar number of SU beds per inhabitants among different macro-areas, the Veneto region formally guarantees uniform access to care in the SU. Instead, access to IVT and/or MT for ischemic stroke is heterogeneous among different macro-areas. Since 2016, a new era has begun for the treatment of LVO-related stroke after five trials showed the effectiveness of EVT within 6 h from symptoms onset [7–12] and, since 2018, after two trials showed the effectiveness of EVT up to 16 and 24 h using advanced imaging [13, 14]. However, since its establishment in 2008, the stroke network of the Veneto region has not undergone changes. Because all patients should have uniform access to revascularization therapies for acute stroke, the regional system of care is called to reorganize himself. Equipping automated CTI analysis software should be mandatory for all Hubs and Spokes; it would be the fastest solution for the centralization of patients from Spokes to Hubs. Transferring interventional neuroradiologists to primary stroke centers to perform mechanical thrombectomy (“drip-and drive”) could be feasible. In order to guarantee a 24 h/7 d coverage, the strengthening of all Spokes and some Hubs should be the ideal solution. Alternatively, the regional health system should envisage a new “hub-and-spoke” model providing the centralization of all stroke patients eligible to revascularization treatments in the Hubs and a new role of Spokes in the immediate post-acute management of ischemic stroke. Finally, an update of the Action Plan for Stroke in Europe by 2030 should be required to redefine new more ambitious treatment target rates of IVT and MT based on current access in the most virtuous macro-areas. This is also because the number of ischemic stroke patients eligible to revascularization treatments is destined to increase with extending time window for treatment IVT and MT using advanced imaging according to new guidelines [15, 16].

Conclusions

Treatment target rates of IVT and MT set by Action Plan for Stroke in Europe 2018–2030 have been globally exceeded in the Veneto region. However, access to revascularization treatments for ischemic stroke is heterogeneous among different macro-areas. Further efforts should be made to homogenize the current territorial organization.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10072-023-06662-7>.

Data Availability Anonymized data will be shared by request from any qualified investigator.

Declarations

Ethical approval The present study was in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Informed consent Informed consent to use anonymized and aggregated data for participation in the studies including stroke patients treated with acute revascularization treatments was obtained from all the patients of each center.

Competing interests The authors declare no competing interests.


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