Mechanical Thrombectomy in and Outside the REVASCAT Trial

Insights From a Concurrent Population-Based Stroke Registry

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Background and Purpose—Recent trials have shown the superiority of endovascular thrombectomy (EVT) over medical therapy alone in certain stroke patients with proximal arterial occlusion. Using data from the Randomized Trial of Revascularization With Solitaire FR Device Versus Best Medical Therapy in the Treatment of Acute Stroke due to Anterior Circulation Large Vessel Occlusion Presenting Within 8-Hours of Symptom Onset (REVASCAT) and a parallel reperfusion treatment registry, we sought to assess the utilization of EVT in a defined patient population, comparing the outcomes of patients treated in and outside the REVASCAT trial.

Methods—SONIIA [Sistema Online d'Informació de l'Ictus Agut], a population-based, government-mandated, prospective registry of reperfusion therapies for stroke encompassing the entire population of Catalonia, was used as data source. The registry documents 5 key inclusion criteria of the REVASCAT trial: age, stroke severity, time to treatment, baseline functional status, and occlusion site. We compared procedural, safety, and functional outcomes in patients treated inside and outside the trial.

Results—From November 2012 to December 2014, out of 17 596 ischemic stroke patients in Catalonia (population 7.5 million), 2576 patients received reperfusion therapies (17/100 000 inhabitants-year), mainly intravenous thrombolysis only (2036). From the remaining 540 treated with EVT, 103 patients (out of 206 randomized) were treated within REVASCAT and 437 outside the trial. Of these, 399 did not fulfill some of the study criteria, and 38 were trial candidates (8 treated at REVASCAT centers and 30 at 2 non-REVASCAT centers). The majority of procedural, safety, and functional outcomes were similar in patients treated with EVT within and outside REVASCAT.

Conclusions—REVASCAT enrolled nearly all eligible patients representing one third of all patients treated with EVT. Patients treated with EVT within and outside REVASCAT had similar outcomes, reinforcing the therapeutic value of EVT.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01692379.

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Key Words: acute stroke ■ clinical trial ■ registry ■ reperfusion ■ thrombectomy

Recent trials have shown the superiority of endovascular thrombectomy (EVT) over medical therapy alone in certain stroke patients with proximal arterial occlusion.[1–5] The generalizability of these results is not yet established because these trials included relatively homogeneous populations of patients with moderate to severe strokes caused by proximal occlusions in the anterior circulation. The Randomized Trial of Revascularization With Solitaire FR Device Versus Best Medical Therapy in the Treatment of Acute Stroke due to Anterior Circulation Large Vessel Occlusion Presenting Within 8-Hours of Symptom Onset (REVASCAT, ClinicalTrials.gov number, NCT01692379) trial[5] had information with regards to the number of patients treated outside of the trial at participating centers and the reasons for exclusion.

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REVASCAT investigated the benefit of mechanical thrombectomy with the Solitaire FR device in addition to best medical therapy (including intravenous tissue-type plasminogen activator [tPA]) compared with best medical therapy alone in patients with acute large vessel stroke.[5] The study was undertaken in Catalonia (Spain), and participating centers were the 4 largest regional tertiary hospitals recognized by the Catalan health authorities as comprehensive stroke centers (CSC). In 2011, the Stroke Program of Catalonia, a health administration plan that seeks to improve quality of stroke care and outcomes, launched a mandatory registry (Sistema Online d'Informació de l'Ictus Agut [SONIIA]) to monitor the quality of reperfusion therapies for acute ischemic stroke (AIS). The registry occurred in parallel with REVASCAT capturing patients within the exact catchment area as REVASCAT, including those treated in the trial.

In this study, we used data from the SONIIA registry and the REVASCAT trial to assess the utilization of EVT in a defined patient population, to assess the reasons for exclusion of patients from the REVASCAT trial, and to compare the outcomes of patients treated in REVASCAT with those treated outside the trial.

Methods

Since January 2011, all AIS patients treated with any reperfusion treatment modality (EVT±intravenous tPA) are being entered into the SONIIA registry, a population-based, government-mandated, prospective database. The registry is subject to annual external audits to ensure completeness. Consecutive inclusion of patients in the SONIIA registry is annually monitored by members of the Stroke Program otherwise not involved in stroke care. Using data from the Hospital Discharge Database for the period of interest and based on specific *International Classification of Diseases, Ninth Revision* diagnostic and procedure codes, we identify overall and by hospital ischemic stroke admissions that received any reperfusion therapy during admission. The Hospital Discharge Database is a health administration data set used for hospital reimbursement that contains information on all admissions, as well as the procedures performed. Stroke admissions (with reperfusion therapies) retrieved this way are cross-checked with the information available in the SONIIA registry for the same period. Undeclared cases are identified and hospitals requested to retrospectively include them in the registry to eventually have a nonbiased view of the quality of reperfusion therapies performed in the territory defining this population of 7.5 million inhabitants.[6] Hospitals with capacity to deliver reperfusion treatments for stroke within the stroke network of publicly financed centers in Catalonia include cases through a web-based tool. This network concentrates almost all reperfusion therapies delivered for AIS after the government of Catalonia commissioned the Stroke Program to organize acute stroke care in 2006 to cover the entire Catalan population. Data from the health administration database that includes all acute hospitalizations in public and private centers show that between 2011 and 2014, private hospitals performed 4 (0.0001%) intravenous thrombolyses and 3 (0.002%) EVT out of 4266 intravenous thrombolyses and 1143 EVT recorded in public centers. Additionally, per Catalan health authorities mandated protocol, all stroke alerts with emergency medical services involvement are transferred to the nearest public hospital with capacity to perform intravenous tPA. Thus, the Catalan network of public stroke treating hospitals includes community hospitals operating via telestroke, primary stroke centers, and CSCs. The first 2 hospital categories contribute to SONIIA intravenous thrombolysis cases only, whereas CSCs perform and report data on intravenous tPA and EVT. In the 4 REVASCAT centers, EVT was done by the same teams within and outside the trial. The 2 additional centers that only treated patients outside the trial were also accredited as CSCs by the Catalan Health Authorities and used similar protocols (we provide details of the procedures in the results).

The registry is linked to the Health Insurance Population Registry of Catalonia, which is universally available for all residents, so that once the Health ID is entered, the system automatically retrieves all sociodemographic data available for that person. Inclusion of noninsured (nonresidents) people is also performed in every case. After having satisfied this initial step, stroke neurologists are required to enter a basic set of clinical, neuroimaging, and outcome variables at baseline, at 24 to 36 hours, and at 3 months.[6]

The SONIIA registry satisfies all legal requirements mandated by the local law regarding protection of personal data. All patients or their surrogate provided written informed consent before the endovascular procedure (whether experimental or routine) and data entry in the registry.

Ascertainment of REVASCAT Eligibility and Failures of Enrollment

Throughout the REVASCAT trial, patients randomized to the active arm of the trial were also included in the SONIIA registry as were all patients treated with EVT under routine practice. To guarantee that their participation in the trial was fully masked, the registry did not include any information to identify patients as REVASCAT ones. We used the registry as a data source for regularly monitoring the number of EVT patients who satisfied basic REVASCAT entry criteria. By comparing that number to the number of patients randomized in the active arm (randomization ratio: 1:1), we obtained periodic estimates of the number of patients enrolled into the active arm versus potentially eligible but treated outside of the trial. The registry coordinator attended the REVASCAT steering committee meetings regularly to give feedback on the proportion of EVT patients eligible for REVASCAT identified through the registry.

Once the REVASCAT steering committee decided to terminate the trial based on the Data and Safety Monitoring Board recommendation, we used registry data to identify all patients who underwent EVT within the REVASCAT period (November 24, 2012, to December 12, 2014) at the 6 hospitals performing EVT in Catalonia. We then applied REVASCAT inclusion criteria to the whole sample to identify all eligible patients both at REVASCAT participating hospitals and at non-REVASCAT centers. The REVASCAT inclusion criteria applicable to the registry data were (1) age ≥18 and ≤80 years; (2) prestroke modified Rankin scale score 0 or 1; (3) stroke severity measured with the National Institutes of Health Stroke Scale (NIHSS) before angiography ≥6; (4) intracranial internal carotid artery (distal internal carotid artery or T occlusions), M1, or tandem occlusions with a pretreatment modified thrombolysis in cerebral ischemia score 0 or 1; and (5) time from last seen to groin puncture ≤8 hours.[5] Because the age criterion was extended in June 2014, we adapted our search algorithm accordingly. Every 3 months throughout the trial, in preparation for the upcoming steering committee meeting, the list of cases retrieved by this search algorithm was identified using the anonymous registry ID number and forwarded to each REVASCAT hospital. Authorized local investigators reviewed each case in the list preserving anonymity rights and sent back aggregated information about the number of REVASCAT-endovascular cases in the list and reasons for exclusion among the remaining REVASCAT eligible (nonrandomized) patients. These anonymized cases were reviewed at each REVASCAT steering committee meeting to ensure compliance with enrollment. Importantly, we were aware that using registry data to detect REVASCAT eligible cases could overestimate the number of patients who met the inclusion criteria because some relevant clinical and neuroimaging features (eg, laboratory deviations, pretreatment Alberta Stroke Program Early CT score (ASPECTS) score. were not recorded in the registry.

For exploratory analysis comparing the safety and efficacy of thrombectomy in and outside the trial, we defined several subgroups of patients who differed from patients treated in REVASCAT in only one criterion and a group of patients who differed in more than one criterion.

Statistical Analysis

We used descriptive statistics. All analyses were performed with STATA 11.1.

Results

Within the REVASCAT enrollment period (roughly 2 years), 17596 ischemic strokes occurred in Catalonia. Of these, 206 patients were included in the trial (103 in each arm) and 2576 AIS patients received reperfusion therapies, resulting in an aggregated reperfusion treatment rate of 17/100000 inhabitants-year (15.6% of all AIS admissions within the study period). Of those, 2036 (79%) received intravenous thrombolysis only, and the remaining 540 (21%) underwent EVT (combined intravenous tPA+EVT: 260 cases). Figure 1 shows a flow chart of EVT patients treated in Catalonia during REVASCAT, of whom 464 (86%) were treated at REVASCAT hospitals.

Reasons for Exclusion From the Trial

According to registry data, among 437 EVT performed outside REVASCAT, 340 were ineligible. Reasons for ineligibility were treatment later than 8 hours (n=75), age criteria (n=33), M2 occlusion (n=36), basilar artery occlusion (n=27), patients with differences in >1 of these inclusion criteria (n=97), and a heterogeneous group (n=72) of patients with mild strokes, poor functional status before the qualifying stroke, and extracranial or distal intracranial occlusions. Of the 97 apparently eligible patients, 30 were treated at non-REVASCAT hospitals and 67 in REVASCAT hospitals. In the latter, 59 had additional reasons for ineligibility not captured by SONIIA: different occlusion site (n=19); comorbidity not recorded in the registry (n=12); patient unlikely to be available for follow-up, mainly non-residents (n=7); informed consent not available (n=6); last time seen well unknown (n=6); other clinical conditions (n=6); and low ASPECTS score (n=3). Thus, the number of patients that eluded randomization was 8/214 (3.7%) at REVASCAT centers and 38/244 (15.6%) in the entire study population.

Characteristics of Patients Treated in and Outside the Trial

We explored the characteristics of patients included in the trial and those in the main subgroups of patients excluded from the trial (Table). The main baseline differences were those derived by the definition of the exclusion criteria (ie, patients over 80 years had higher average age) and the subgroups (ie, patients in the older age category had lower proportion of modified Rankin scale 0 before stroke or patients in the M2 occlusion group had lower baseline severity). Table shows that EVT modalities and procedural results were similar for patients inside and outside the trial, including door to puncture times. Regarding safety outcomes, there were a few more hemorrhages in the M2 and basilar groups, but the absolute numbers were low. Mortality was only increased in the basilar group and was rather low in some of the other subgroups. The 3-month functional outcomes were similar in most groups of patients treated with thrombectomy and superior to those seen in the medical arm of the REVASCAT trial (Figure 2).

Discussion

In this report, we provide information about the extent to which REVASCAT findings apply to the overall population studied (the Catalan population) and an estimate of potential eligible patients for EVT within a defined study population over a 2-year period. The inclusion of the vast majority of eligible patients within the target population[7] supports the validity of REVASCAT results for the whole Catalan population because the majority of the treatments were performed in REVASCAT centers. The similar safety results in patients treated in and outside REVASCAT are reassuring for the routine use of mechanical thrombectomy. Furthermore, our findings suggest that applying similar indications of mechanical thrombectomy as those used in Catalonia during REVASCAT might increase the number of patients who benefit from thrombectomy by ≤3× of those included in the recently published trials.

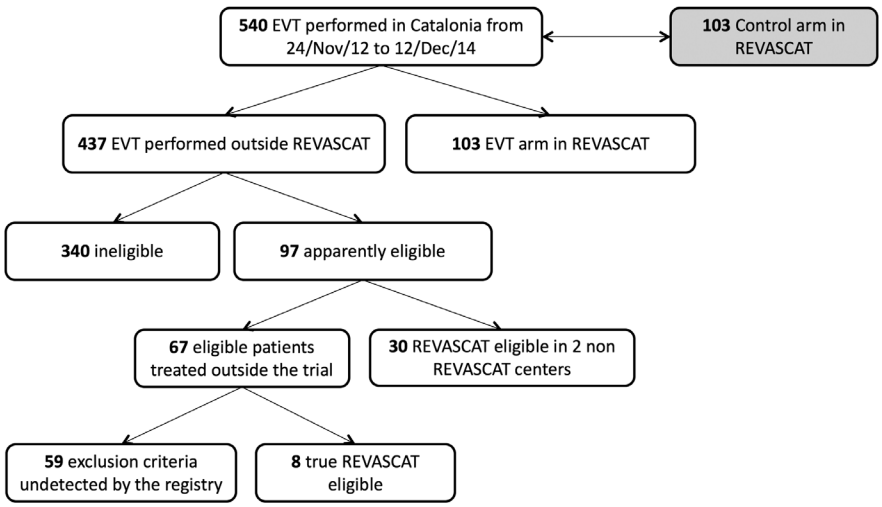

Figure 1. Flow chart of endovascular thrombectomy (EVT) performed throughout the Randomized Trial of Revascularization With Solitaire FR Device Versus Best Medical Therapy in the Treatment of Acute Stroke due to Anterior Circulation Large Vessel Occlusion Presenting Within 8-Hours of Symptom Onset (REVASCAT) trial.

Table. Characteristics of the REVASCAT Trial Patients and Other Patients Treated Outside the Trial

	Randomized Control (n=103)	Randomized EVT (n=103)	Apparently Eligible, Not Randomized (N=97)	Older Than Age Cutoff (n=33)	M2 Occlusion (n=36)	Basilar Occlusion (n=27)	OTP >8 h (n=75)	>1 difference (n=97)	Miscelanea (n=72)
Age, mean (SD)	67.2 (9.5)	65.7 (11.3)	62.8 (14)	83 (1.6)	67.1 (10.6)	66.4 (15.2)	64.1 (13.2)	71.2 (13.5)	65.9 (13.7)
Sex, women	49 (47.6)	48 (46.6)	38 (39.2)	20 (60.6)	16 (44.4)	8 (29.6)	41 (54.7)	45 (46.4)	29 (40.3)
Premorbid mRS									
0	83 (80.6)	86 (83.5)	82 (84.5)	23 (69.7)	30 (83.3)	25 (92.6)	63 (84)	51 (52.6)	49 (68.1)
1	20 (19.4)	17 (16.5)	15 (15.5)	10 (30.3)	6 (16.7)	2 (7.4)	12 (16)	15 (15.5)	7 (9.7)
Baseline NIHSS, median (IQR)	17 (12–19)	17 (14–20)	18 (14–20)	16 (12–21)	13 (10–20)	27 (14–35)	16 (13–20)	13 (7–21)	16 (12–21)
Occlusion site									
ICA-T	27 (26.7)	26 (25.5)	22 (22.7)	11 (29)	…	…	10 (13.3)	4 (4.1)	7 (9.7)
M1 MCA	65 (64.4)	66 (64.7)	49 (50.5)	21 (55.3)	…	…	50 (66.7)	10 (10.3)	35 (48.6)
Tandem occlusions	13 (12.9)	19 (18.6)	26 (26.8)	4 (12.1)	…	…	15 (20)	3 (3.1)	6 (8.3)
Treatment modality									
Mechanical thrombectomy	…	97 (94.2)	87 (89.7)	30 (90.9)	30 (83.3)	22 (81.5)	70 (93.3)	84 (86.6)	63 (87.5)
Thrombectomy+IA thrombolysis	…	1 (1.0)	8 (8.3)	3 (9.1)	4 (11.1)	4 (14.8)	3 (4)	5 (5.2)	2 (2.8)
IA thrombolysis	…	0	1 (1)	0	2 (5.6)	1 (3.7)	0	3 (3.1)	1 (1.4)
Diagnostic-only angiography	…	5 (4.8)	1 (1)	1 (2.6)	0	0	2 (2.7)	5 (5.2)	6 (8.3)
OTP min, median (IQR)	…	269 (201, 340)	223 (165–305)	220 (150, 305)	222 (175–287)	310 (220–375)	693 (577–885)	590 (261–798)	196 (148–270)
DTP min, median (IQR)	…	110 (87–167)	115 (78–165)	84 (65–130)	148 (115–190)	117 (65–168)	109 (84–145)	125 (81–180)	118 (80–167)
Postprocedure mTICI 2b, 3*	…	82 (79.6)	78 (80.4)	25 (75.8)	29 (80.6)	21 (77.8)	59 (78.7)	76 (78.4)	60 (83.3)
Procedural complications									
Distal embolization	…	5 (4.9)	2 (2.1)	2 (6.1)	0	0	2 (2.7)	1 (1)	1 (1.4)
Arterial dissection	…	4 (3.9)	4 (4.1)	0	0	1 (3.7)	4 (5.3)	3 (3.1)	1 (1.4)
Arterial perforation	…	5 (4.9)	0	0	0	2 (7.4)	0	3 (3.1)	0
Other	…	16 (15.5)	9 (9.3)	2 (6.1)	3 (8.3)	1 (3.7)	2 (2.7)	3 (3.1)	6 (8.3)
sICH (SITS-MOST)	1.9	2 (1.9)	2 (2.1)	0	2 (5.6)	2 (7.4)	2 (2.7)	3 (3.1)	1 (1.4)
Death at 3 mo	15.5	19 (18.4)	16 (16.5)	7 (21.2)	2 (5.6)	12 (44.4)	7 (9.3)	20 (20.6)	7 (9.7)

Numbers express n (%) unless otherwise stated. DTP indicates door to puncture time; EVT, endovascular thrombectomy; ICA-T, internal carotid artery terminus; M1 MCA, M1 segment of the middle cerebral artery; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; OTP, onset to puncture time; REVASCAT, Randomized Trial of Revascularization With Solitaire FR Device Versus Best Medical Therapy in the Treatment of Acute Stroke due to Anterior Circulation Large Vessel Occlusion Presenting Within 8-Hours of Symptom Onset; sICH, symptomatic intracerebral hemorrhage; SITS-MOST, Safe Implementation of Thrombolysis in Stroke Monitoring Study; and TICI, thrombolysis in cerebral ischemia.

*According to local investigators.

Although undoubtedly representing the most valid form of data generation for comparing treatments, randomized trials can lack transportability to other settings or selection criteria. Linking randomized trials to registries is thought to represent a novel, improved form of evidence generation that combines the advantages of methodological rigor imposed by randomized trials with applicability of findings to larger population conferred by registries.[8] This information distinguishes REVASCAT from previous trials and addresses one major remaining concern related to EVT for stroke: that of applicability in general practice.

We think that our findings are highly relevant for further planning of stroke systems of care because as a result of the dramatic benefit of EVT demonstrated by the recent randomized trials in selected populations, endovascular stroke therapy is likely to be widely adopted by multiple healthcare systems around the world. In that respect, given the 540 patients treated over 2 years in a population of 7.5 million, to which the 103 patients randomized to control in REVASCAT should be added, we estimate a current EVT utilization rate of 4.3/100 000 inhabitants-year, roughly 4% of all AIS admissions during the trial (17 596 patients). This figure will likely

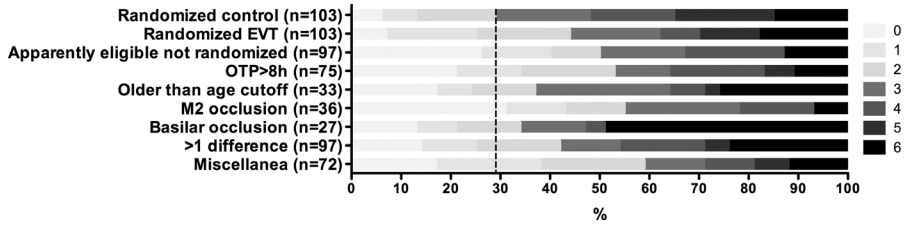

Figure 2. Functional outcome of different subgroups of patients treated in and outside the Randomized Trial of Revascularization With Solitaire FR Device Versus Best Medical Therapy in the Treatment of Acute Stroke due to Anterior Circulation Large Vessel Occlusion Presenting Within 8-Hours of Symptom Onset (REVASCAT) trial. The vertical line indicates the proportion of patients with modified Rankin Scale score (mRS) 0 to 2 in the medical arm of the REVASCAT trial. With the exception of an excess of mortality in patients with basilar occlusion, the distribution of mRS scores is favorable in all subgroups of patients treated with endovascular thrombectomy (EVT) compared with patients randomized to the control arm in REVASCAT. OTP indicates onset to puncture time.

increase in the future in view of the mounting evidence of dramatic benefit with EVT.

Outcomes were similar across different patient subgroups, which reinforce the value of mechanical thrombectomy in a wide range of stroke patients not necessarily fulfilling all the inclusion criteria of recent trials. The functional outcome assessment in the SONIIA registry was neither blinded nor done centrally with a video recording of the modified Rankin scale assessment as in the trial, but the strong correlation of video-based assessments in REVASCAT with the assessments performed by the same personnel performing assessments in SONNIA (Lopez-Cancio E, et al, unpublished data, 2015) suggests that those small differences in the modified Rankin scale assessment cannot account for the better outcomes in patients treated with EVT outside the trial compared with control patients in REVASCAT. In summary, it is likely that other patients do benefit from thrombectomy as long as the treatment is done as in the recent endovascular trials using stentriever devices and treating patients as expeditely as possible. However, it is necessary to remark also that these results refer mainly to treatments performed at high volume CSCs with extensive experience and proven capabilities in all aspects of the complex AIS patient care.

In addition, we think that the existence of a concurrent, mandatory registry allowing feedback regarding rates of patients treated outside of the trial along with equipoise among all investigators have been key ingredients to ensuring such high enrollment rates in REVASCAT. This trial enrolled 206 patients at 4 centers over 2 years, yielding a rate of 2.1 patients per center per month, the highest recruitment rate of all other randomized endovascular trials.

This study is not without limitations. Given that our registry only captures patients treated with reperfusion therapies, it is difficult to estimate the proportion of untreated patients who would have satisfied REVASCAT entry criteria. However, because Catalonia has a well-organized system of acute stroke care with good access to expert care throughout the entire region, we estimate it to be low. The low number of REVASCAT eligible patients treated outside the trial provides evidence of no further concealed selection criteria within the trial, but we cannot guarantee that patients who did not meet REVASCAT eligibility criteria were not selected for EVT according to other prognostic criteria. Finally, for the sake of simplicity, our registry sacrificed a number of variables, including ASPECTS score. Patients with low ASPECTS scores were generally excluded from the treatment, and for this reason, our study does not provide evidence about the treatment of patients with different characteristics, such as large ischemic cores. The absence of information, such as ASPECTS scores, also posed further difficulties at the time of determining trial eligibility, which could only be addressed at REVASCAT participating centers. Because all patients treated at non-REVASCAT centers and satisfying basic REVASCAT inclusion criteria were considered trial eligible, the 15.6% calculated is likely to overestimate the proportion of truly eligible patients treated outside the trial in the whole population.

In conclusion, this study provides further evidence of the benefit of EVT seen in recent mechanical thrombectomy trials. The inclusion of most eligible patients in the trial shows that there was no major bias during the conduction of the REVASCAT trial, and the similar outcomes in patients not fulfilling all the inclusion criteria in REVASCAT suggests that EVT may be beneficial for a wider range of patients when it is performed in experienced centers.

Appendix

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