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Quality of Life after Intra-arterial Therapy for Acute Ischemic Stroke

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Abstract

Few data exist about health-related quality of life outcomes after intra-arterial therapy for acute ischemic stroke. We assessed stroke-specific quality of life in stroke survivors after intra-arterial therapy. Consecutive patients undergoing intra-arterial therapy for acute ischemic stroke from 2005-2010 were retrospectively identified via an institutional database. Stroke-specific quality of life (using the Stroke-Specific Quality of Life Score) and disability status (modified Rankin Scale) were prospectively assessed via mailed questionnaire. We analyzed quality of life scores by domain and summary score, with a summary score of 4 defined as a good outcome. Analysis of variance was used to model the effect of final recanalization status, stroke severity, and modified Rankin Scale on total quality of life score. ANOVA and Pearson's correlations were used to test the association between stroke severity/modified Rankin Scale and quality of life/time since stroke respectively. Of ninety-nine acute ischemic stroke patients, 61 responded yielding: 11 interim deaths, 7 incomplete surveys, and 43 complete surveys for analysis. Among responding survivors, overall quality of life score was 3.9 (SD 0.7); 77% of these reported good quality of life. Scores were higher in recanalized patients in 11 of 12 domains, but was significant only for mood. Although modified Rankin Scale was associated with stroke severity, quality of life was independent of both. Seventy-seven percent of acute ischemic stroke survivors who received intra-arterial therapy reported good quality of life. Furthermore, these data suggest that stroke-specific quality of life is an independent outcome from stroke severity and disability status.

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Introduction

Treatment in the hyper-acute phase of acute ischemic stroke (AIS) currently focuses on reestablishing blood flow with either intravenous recombinant tissue plasminogen activator (IV tPA)¹ or newer, intra-arterial therapies (IAT) such as angioplasty, mechanical clot extraction, and stenting.² These interventions are not yet FDA-approved for treatment of stroke, but have demonstrated excellent recanalization rates and safety outcomes. While some data support that IV tPA is associated with improved health-related quality of life (HR-QOL)³, little is known about how catheter-based interventions influence overall or disease-specific quality of life. As new devices become available and treatment decision making becomes increasingly complex,⁴ clinically relevant outcome measures such as HR-QOL are essential for understanding the full impact of these treatment modalities.

Among the outcome parameters currently used to establish and compare safety and efficacy of IAT for AIS, the most informative follow-up measures have yet to be definitively established. Pre- and post-procedure blood flow, recanalization, change in NIH Stroke Scale (NIHSS), 90-day mortality, and three month functional measures such as modified Rankin Scale (mRS) and Barthel Index are among the most commonly utilized outcome measures in pivotal intra-arterial trials.⁵ These measures are primarily physician-driven and do not effectively assess patient-centered elements such as social roles, communication, and satisfaction with daily activities. The importance of HR-QOL is becoming increasingly recognized⁶ and the American Society of Interventional and Therapeutic Neuroradiology guidelines now recommend the use of a QOL measure in trials to better assess treatment efficacy.⁷ The aim of this study was to determine disease specific HR-QOL in patients who received IAT after AIS.

Methods

This study utilizes retrospective chart abstraction of patient characteristics from the prospectively-populated institutional stroke registry, combined with prospectively-collected QOL data using the Stroke-Specific Quality of Life scale (SS-QOL), a validated, disease-specific instrument.⁸ This scale was initially developed in English in 1999 and has since been validated in both ischemic⁸ and hemorrhagic stroke,⁹ including use by proxy.¹⁰

Inclusion criteria

Patients were identified using the University of Utah stroke center quality database and included if they suffered AIS between March 2005 to December 2010, received IAT for their acute stroke, and survived to hospital discharge. Medical decision-making was on a case-by-case basis per the discretion of the stroke and neuro-interventional teams. Patients were included regardless of initial administration of IV-tPA. IA therapies of both thrombolysis and thrombectomy were included. Patients were excluded if IAT was for subacute stroke.

Determination of Baseline Characteristics

Once identified, patient demographics and clinical characteristics were abstracted from source documents. Presenting stroke severity was measured by the NIHSS and recorded at

presentation, except for 8 patients in whom the NIHSS was extrapolated retrospectively via a validated method.¹¹ We were unable to extract the NIHSS in 2 patients due to incomplete documentation of presenting exam on transfer. Stroke localization, site of occlusion, and cerebral perfusion pre-and post-IAT were characterized by review of original films (CT, MR, or digital subtraction angiography (DSA)). Stroke subtypes were retrospectively classified using the criteria proposed by the Trial of Org 10172 in Acute Stroke Treatment (TOAST).¹² Outcome measures included recanalization, mRS at discharge and follow-up, stroke recurrence, and QOL. Stroke recurrence and QOL were determined by mailed survey. All outcomes measures are described further below.

Angiographic Outcome Assessment - TICl Scores

Pre- and post-procedure cerebral perfusion were reported using Thrombolysis in Cerebral Infarction (TICI) scores.⁷ TICI scoring is from 0 (no perfusion) to 3 (full perfusion, including distal branches). A fellowship-trained neurointerventionalist [MW] determined TICI scores by review of DSA films. We considered patients with partial (TICI 2a/2b) or complete (TICI 3) recanalization to be successful radiographic outcomes.¹³

Clinical Outcome Assessment – modified Rankin Scale and Stroke-Free Status Questionnaire

The mRS is a widely used assessment instrument of overall functional level.¹⁴ The scale runs from 0 (no symptoms) to 6 (dead), with scores 0-2 generally considered to be good outcomes, based on retained ability to perform complex activities of daily living.¹⁵ Modified Rankin Scale values at discharge and follow-up were abstracted from the chart.

Stroke recurrence since the time of IAT was assessed via the Questionnaire for Verifying Stroke-Free Status (QVSFS), an 8-item questionnaire, and included with the mailing.¹⁶ If any of the 8 items were marked, the patient screened positive (i.e. “not stroke free”). Records from the stroke-like event were requested and reviewed to verify stroke recurrence versus an alternative diagnosis.

Patient Centered Outcome Assessment – Stroke Specific Quality of Life Scale

QOL was assessed utilizing the full 12-domain SS-QOL Scale via a mailed or phone questionnaire.^{8,17} The SS-QOL scale is a disease-specific HR-QOL questionnaire that utilizes 5-point Likert scales, and encompasses 12 domains: energy, family roles, language, mobility, mood, personality, self-care, social roles, thinking, upper extremity function, vision, and work/productivity. Domain scores are reported as an un-weighted mean of the individual questions within each domain. A summary score is calculated as the un-weighted mean of all 12 domain scores, with a range of 1-5.¹⁷ Higher scores indicate better QOL; a summary SS-QOL score 4 is considered a good QOL.¹⁸

Survey Content and Administration

The survey included an informational letter, consent form including request for permission to obtain additional medical records if needed, the QVSFS, and the SS-QOL. To maximize study response rates, we used a systematic method of multiple forms of contact, including a pre-notification letter, followed by a second mailing, consisting of the consent form,

questionnaire, token of appreciation (\$2 cash), and stamped self-addressed return envelope. Patients were also offered the option of requesting help from a trained research coordinator in completing the survey over the telephone.¹⁹ A reminder postcard and follow-up telephone call were extended to remaining non-responders.

Statistical Methods

Statistical analysis was performed with Microsoft Excel and SAS software version 9.3 (SAS Institute, Cary NC). Summary data is presented as means $\pm$ standard deviation (SD) if normally distributed and as medians with inter-quartile range (IQR) if skewed. QOL scores were analyzed by each of the 12 domains and as a summary score, with summary scores dichotomized as < 4 .¹⁸ We used the Wilcoxon sign rank test (a non-parametric equivalent of the t-test) to assess differences in the SS-QOL summary and domain scores by the dichotomized TICI score ($< 2a$ vs. $\geq 2a$) after IAT. This model was run five times, individually adjusting for age, mRS at discharge, time since discharge, presenting NIHSS, and number of comorbidities. The following covariates were treated as categorical variables: age (< 49 , 50-65, and ≥ 66 or older), mRS at discharge (0-1, 2-3, and 4-5), time from discharge (≤ 2 years, > 2 years), and initial NIHSS score (≤ 6 , 7-15, and ≥ 16). The number of co-morbidities was classified as 0, 1, 2 or more. A 2-sided p-value ≤ 0.05 was considered statistically significant. We used analysis of variance (ANOVA) to model the effects of post-IA TICI score on the summary SS-QOL score and that of the initial NIHSS score on subsequent mRS. Pearson's correlation was used to test the association between SS-QOL summary and time elapsed between stroke onset and QOL assessment.

Ethics

The University of Utah Institutional Review Board approved this study. Informed consent was obtained by all participants who completed the survey. In non-responders, consent was waived for review of their clinical information. Proxy consent and survey completion was allowed when needed.²⁰

Results

Demographics and Procedural Outcomes

Between March 2005 to December 2010, 99 consecutive patients who presented with AIS and received IAT at our institution met inclusion criteria and were sent surveys. There were 61 total survey responses (62% overall response rate), 11 of which reported interim deaths and 7 of whom were unable to complete the surveys, yielding a total of 43 completed surveys (43% of hospital survivors of IAT) for further analysis. Interim time from presentation to survey was a median of 2.3 years [range 0-5, IQR 1.5-3.5]. Of these, 52% were female, the mean age was 61 (SD 16) years, and the median initial NIHSS was 14 (IQR 9, 18). The most common stroke subtype was cardioembolic (49% of all patients). Seventy-two of all patients (73%) were recanalized based on TICI scoring criteria. Clinical characteristics of the patients are summarized in Table 1.

Stroke Recurrence

Thirteen of the 43 (30%) responses to the QVSFS screened positive (i.e. potentially *not* stroke-free). After review of relevant medical records, 9 were determined to be recurrence free: 4 were suspected “unmasking” (worsening of old deficits due to systemic reasons such as infection or other cause) and 5 responses referred to prior stroke symptoms. We were unable to determine a diagnosis in 2 patients who screened positive: 1 was not seen by medical providers at the time of symptoms and 1 declined release of medical records. Two patients had definite recurrent stroke (4.7%). Thus, possible or definite recurrent stroke was identified in 4 of the 43 respondents (9.3%).

Quality of Life and Functional Outcomes

The mean overall summary SS-QOL score among the surviving respondents was 3.9 (SD 0.7). Thirty-three patients reported good QOL (summary score ≥ 4), 77% of the 43 surviving respondents and 33% of the entire sample to whom surveys were sent. The domains with the highest reported QOL were mood, vision, and self-care; the lowest were in thinking, energy levels, and social roles.

While 11 of the 12 individual SS-QOL domain scores were higher in surviving recanalized patients than in surviving non-recanalized patients, these differences were not significant with the exception of mood ($p < 0.017$) (Table 2). The QOL score results are graphed by domain and recanalization status in Figure 1. After adjusting individually for age, mRS at discharge, time since discharge, initial NIHSS or number of comorbidities, recanalization status remained not predictive of SS-QOL (Table 3).

In surviving respondents, mean SS-QOL was similar across NIHSS severity subgroups, however mRS was higher with higher initial NIHSS (ANOVA F value = 4.54, 1 DF, $p=0.039$) (Figure 2). SS-QOL summary score was not associated with time elapsed between stroke onset and QOL assessment ($p = 0.667$) (Figure 3).

Discussion

This study reveals that 77% of the responding stroke survivors who underwent IAT for AIS at our institution report a good HR-QOL. In this group, overall QOL scores were not influenced by stroke severity or functional status (mRS), supporting the role of QOL assessment as an independent factor in traditionally assessed stroke outcomes.

Comparisons of our results with other QOL studies in stroke are limited due to variability of QOL instruments, heterogeneous patient selection, and social/cultural influences. To our knowledge, the only other studies to specifically assess QOL after IAT used non-disease specific measures. Fischer evaluated QOL using the EuroQOL in multi-modal IAT patients and reported good QOL in 56% of stroke survivors, with a high presenting NIHSS and internal carotid artery occlusion being independent predictors of impaired QOL.²¹ Ottomyer evaluated functional and QOL outcomes after IAT for acute basilar artery occlusion and found that 75% of survivors in their study reported a favorable functional outcome measured by mRS and an acceptable QOL measured by the 36-Item Short-Form Health Survey.²²

While some have suggested an association between functional outcomes and HR-QOL in stroke survivors overall,^{23,24} and studies specific to IAT have shown that recanalization may be positively correlated with improved mRS score,²⁵ our findings do not support a clear association between mRS and QOL in those receiving IAT. Fischer reported an overall correlation of handicap and QOL (as measured by mRS, Barthel Index, and EuroQol scales), although mixed findings between functional outcome and QOL remained, with some highly functional patients reporting impaired QOL and others with severe functional impairment reporting good QOL.²¹ Our findings also show that while functional outcomes are highly associated with initial stroke severity, SS-QOL is not (Figure 2). These findings highlight the importance of measuring both functional and patient-centered outcome measures, which likely reflect different variables.

In this study, each QOL domain showed a higher QOL in those recanalized versus those who were not, though this difference was significant only in mood. However, total infarct volume, not recanalization status, is currently the favored positive predictor of 90-day clinical outcomes in patients receiving endovascular therapies for stroke.²⁶ We did not analyze final infarct size in our patients, and thus may have included patients who had futile recanalization. It is possible that a higher QOL could be demonstrated in patients who had both successful recanalization and a resultant small infarct volume.

While our study was not designed to reliably assess effect of comorbidities or changes of perceptions over time (“response-shift”),²⁷ there is some evidence that perception of QOL may evolve at different time points following hospital discharge,^{28,29} particularly in the presence of new and/or pre-morbid diseases that may influence QOL and/or functional outcomes.^{30,31} Response-shift is an important concept when considering the routine measurement of QOL outcomes, including the importance of pre-morbid and follow-up QOL assessment, and may warrant serial QOL assessment where feasible. In this case, there is no reliable mechanism to assess pre-stroke QOL, and our study was not powered, nor designed, to follow change in QOL over time. Nonetheless, we did not observe a significant relationship between reported QOL and time elapsed since stroke, despite a wide range of follow-up lengths (range 0-5 years) (Figure 3).

Additional limitations of this study include our inability to decipher effect of stroke location or treatment modality on QOL, as our sample was underpowered to do so. This includes limited information regarding specific patient deficits that may have prompted surrogate completion of the survey, such as aphasia, cognitive dysfunction, visual impairment, or other functional barrier to patient completion. It is known that surrogate responses to QOL surveys differ from patient responses; however, typically surrogate respondents rate QOL worse than patients,³² which would potentially bias our results towards worse QOL. Baseline caregiver characteristics may also have an important influence on stroke survivor QOL,³³ and evaluation of these parameters was beyond the scope of this study. Strengths include our use of validated, disease-specific instruments for outcomes measures, as well as multiple methods of contact to reach patients, which resulted in a 62% overall response rate, and 43 surveys with analyzable QOL responses (43% of the total sample).

Summary and Conclusion

We analyzed QOL as reported by stroke survivors who have received IAT for AIS. Despite our small sample size, our data provides useful information regarding the spectrum of reported QOL in this patient group. Our study provides insight into patient-specific outcomes of IAT and provides a foundation for future, modality-specific, controlled investigations. Our data supports the notion that QOL assessment provides additional outcome information, separate from functional outcome scales, time elapsed since stroke, and initial stroke severity. It is our hope that these results will compel more routine and widespread collection of QOL measures.

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Figure 1.

SS-QOL by domain after intra-arterial therapy (n=43): recanalized (TICI ≥ 2) vs. non-recanalized (TICI < 2). Horizontal edges of box=25th and 75th percentiles, center line=median, marker=mean, whiskers are minimum and maximum. * Indicates $p < 0.05$. SS-QOL=Stroke-specific quality of life; TICI=Thrombolysis in Cerebral Infarction.

Figure 2.

Mean Summary SS-QOL and mRS by NIHSS among Surviving Respondents. Error bars represent standard deviation.

GE=greater than or equal; mRS=modified Rankin scale; NIHSS=NIH Stroke Scale; SS-QOL=Stroke-specific quality of life.

Figure 3.
Summary SS-QOL by time since stroke.
SS-QOL=Stroke-specific quality of life.

Table 1

Clinical characteristics of patients.

	All Patients (n=99)	Survey Respondents (n=43)	Non-Respondents (n=56)
Age in years at stroke onset, mean, (SD)	61 (16)	59(15)	63 (16)
Female, %	52	56	49
Initial NIHSS Score, median (IQR)	14(9,18)	11(9,18)	15(10,18)
Rates of recanalization, n TICI 2a (%)	72 (73)	31 (74)	41(72)
Discharge mRS, median (IQR)	3 (2,4)	3 (1,4)	4 (3,5)
Stroke Risk Factors, n (%)			
Hypertension	55 (56)	23 (54)	32 (57)
Diabetes	19(19)	6(14)	13 (23)
Dyslipidemia	34 (34)	14(33)	20 (36)
Smoking	28 (28)	6(14)	22 (39)
Mechanical heart valve	1(1)	0(0)	1(2)
Past Stroke	11(11)	3(7)	8(14)
Atrial Fibrillation	35 (35)	16(37)	19(34)
Site of Occlusion, n (%)			
Left ICA/MCA	47 (48)	22 (51)	25 (45)
Right ICA/MCA	38 (38)	15 (35)	23 (41)
Basilar	13(13)	6(14)	7(13)
PCA	1(1)	0(0)	1(2)
Etiology (TOAST), n (%)			
Large artery Atherosclerosis	8(8)	1(2))	7(12)
Cardioembolic	49 (49)	23 (54)	26 (46)
Lacunar	0(0)	0(0)	0(0)
Other determined etiology	11(H)	9(21)	2(4)
Undetermined 2 or more causes	15(15)	4(9)	11(19)
Undetermined negative evaluation	14(14)	6(14)	8(14)
Undetermined incomplete evaluation	2(2)	0(0)	2(4)

ICA=internal carotid artery; IQR=interquartile range; MCA=middle cerebral artery; mRS=modified Rankin scale; NIHSS=NIH Stroke Scale; PCA=posterior cerebral artery; QOL=quality of life; TOAST=Trials of Org in Acute Stroke Treatment; TICI=Thrombolysis in Cerebral Infarction.

Table 2

SS-QOL Scores overall and by domain.

	SS-QOL Scores in All Survey Respondents (n=43)			SS-QOL in Survey Respondents by Postprocedure TICI score			
	Mean $\pm$ SD	Median (IQR)		<2 (n=11)		2 (n=32)	
				Mean $\pm$ SD	Median (IQR)	Mean $\pm$ SD	Median (IQR)
Summary Score	3.9 $\pm$ 0.7	3.9(3.5 - 4.4)		3.7 $\pm$ 0.6	3.8(3.2 - 4.2)	4.0 $\pm$ 0.7	3.9(3.6 - 4.6)
Energy	3.5 $\pm$ 1.3	3.3(2.3 - 4.7)		3.0 $\pm$ 0.9	2.7(2.3 - 3.7)	3.6 $\pm$ 1.3	4.2(2.5 - 4.8)
Family Roles	3.6 $\pm$ 1.1	3.7(2.7 - 4.3)		3.2 $\pm$ 1.0	3.3(2.3 - 4)	3.7 $\pm$ 1.1	3.7(2.8 - 4.7)
Language	4 $\pm$ 0.9	4.2(3.4 - 4.8)		3.6 $\pm$ 1.1	4.0(2.2 - 4.2)	4.1 $\pm$ 0.8	4.3(3.6 - 4.8)
Mobility	4.0 $\pm$ 1.0	4.3(3.3 - 5.0)		3.7 $\pm$ 1.2	3.7(3.0 - 5.0)	4.1 $\pm$ 0.9	4.4(3.5 - 5.0)
Mood	4.1 $\pm$ 0.8	4.2(3.8 - 4.8)		3.8 $\pm$ 0.5	3.8(3.4 - 4.4)	4.2 $\pm$ 0.9	4.4(4.0 - 4.8)
Personality	3.6 $\pm$ 1.1	3.7(2.7 - 4.7)		3.3 $\pm$ 0.5	3.3(3 - 3.7)	3.7 $\pm$ 1.2	3.8(2.7 - 5.0)
Self-care	4.6 $\pm$ 0.6	4.8(4.2 - 5.0)		4.3 $\pm$ 0.8	4.4(4.0 - 5.0)	4.7 $\pm$ 0.5	5.0(4.7 - 5.0)
Social Roles	3.2 $\pm$ 1.1	3.0(2.4 - 4.2)		3.1 $\pm$ 1.0	2.6(2.2 - 3.8)	3.3 $\pm$ 1.2	3.1(2.4 - 4.4)
Thinking	3.5 $\pm$ 1.3	3.7(2.7 - 4.7)		3.7 $\pm$ 1.0	3.7(2.7 - 4.7)	3.4 $\pm$ 1.4	3.7(2.5 - 4.8)
Arm function	4.0 $\pm$ 0.8	4.2(3.4 - 4.6)		3.7 $\pm$ 1.2	3.4(3.0 - 5.0)	4.1 $\pm$ 0.7	4.3(3.6 - 4.6)
Vision	4.7 $\pm$ 0.5	5.0(4.5 - 5.0)		4.7 $\pm$ 0.5	5.0(4.7 - 5)	4.7 $\pm$ 0.5	5.0(4.4 - 5.0)
Work/Productivity	3.8 $\pm$ 1.0	4.0(3.0 - 4.7)		3.5 $\pm$ 0.7	3.7(3.0 - 4.0)	3.9 $\pm$ 1.1	4.0(3.3 - 5.0)

* P value for difference by Wilcoxon sign rank test.

IQR=interquartile range; SD=standard deviation; TICI=Thrombolysis in Cerebral Infarction.

Table 3

Mean Summary SS-QOL score by TICI score by given covariate.

	Post-procedure TICI		
	<2	2	
Covariate adjusted for:	Adjusted Mean [95% CI]	Adjusted Mean [95% CI]	P value
NIHSS	3.5 [3.0 - 4.0]	3.9 [3.6 - 4.2]	0.10
Discharge mRS	4.0 [3.6 - 4.3]	4.0 [3.8 - 4.2]	0.80
Age	3.7 [3.2 - 4.1]	4.0 [3.8 - 4.3]	0.14
Time since stroke	3.7 [3.1 - 4.4]	4.1 [3.6 - 4.6]	0.14
# of comorbidities	3.6 [3.1 - 4.0]	4.0 [3.8 - 4.3]	0.07

CI=confidence interval; mRS=modified Rankin scale. NIHSS=NIH Stroke Scale; SS-QOL=stroke specific quality of life; TICI=Thrombolysis in Cerebral Infarction.