Advances in Medical Sciences 63 (2018) 100–106

Contents lists available at ScienceDirect

Advances in Medical Sciences

journal homepage: www.elsevier.com/locate/advms

Original research article

Pharmacological thrombolysis for acute ischemic stroke treatment: Gender differences in clinical risk factors

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ARTICLE INFO

Article history:
Received 6 May 2017
Accepted 31 August 2017
Available online xxx

Keywords:
Gender
Acute ischemic stroke
Recombinant tissue-type plasminogen activator (rtPA)

ABSTRACT

Background: In a stroke population, women have a worse outcome than men when untreated. In contrast, there is no significant difference in treated patients. In this study, we determined whether clinical variables represent a promising approach to assist in the evaluation of gender differences in a stroke population.

Methods: We analyzed data from ischemic stroke patients' ≥18 years-old from the stroke registry on rtPA administration and identified gender differences in clinical factors within inclusion and exclusion criteria in a stroke population that received rtPA. Multivariate analysis was used to adjust for patient demographic and clinical variables.

Results: Of the 241 eligible stroke patients' thrombolytic therapy, 49.4% were females and 50.6% were males. Of the 422 patients that did not receive rtPA, more women (235) were excluded from rtPA than men (187) ($P < 0.05$). In the male population, exclusion from rtPA was associated with history of a previous stroke ($P < 0.05$, OR = 2.028), hypertension ($P < 0.05$, OR = 0.519), and NIH stroke score ($P < 0.0001$, OR = 0.893). In female stroke patients, exclusion from rtPA was associated with previous history of stroke ($P < 0.05$, OR = 2.332), diabetes ($P < 0.05$, OR = 1.88) and NIH stroke score ($P < 0.05$, OR = 0.916).

Conclusions: Despite similarities in different areas of stroke care for both men and women, more women with diabetes, previous history of stroke and higher NIH scores are more likely to be excluded from thrombolytic therapy. Men with a previous history of stroke, hypertension and higher NIH scores are more likely to be excluded rtPA even after adjustment for confounding variables.

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1. Introduction

The differences between men and women in incidence and severity of stroke have been investigated by many studies [1–3]. Findings indicate that women have a higher incidence of stroke, and have increased stroke severity, risk of reoccurrence, and poorer clinical outcome. Gender disparity in the response to thrombolytic treatment during acute ischemic stroke has been extensively debated. Many studies [4–6] have attempted to address gender disparity by investigating the relationship between gender and thrombolytic treatment in acute ischemic stroke patients. Since only a small percentage of patients qualify for treatment with rtPA [1], understanding gender differences in the response to thrombolytic treatment with rtPA is important to increase the use of rtPA in an acute ischemic stroke population [1,7,8].

Several studies have demonstrated that in untreated control populations, women have a worse functional outcome than men [1–3]. However, when treated with thrombolytic therapy, no difference in clinical outcome was observed [9]. This study suggests that the use of rtPA in an acute ischemic stroke population may eliminate gender disparity [4,5,10]. In support of this idea, a recent study by Lasek-Bal et al. [4] found that women treated with rtPA following an acute ischemic stroke improved significantly more than men within 24 h. Although the mechanism for the improvement in women is not fully understood, one possibility is that women have a higher percentage of cardioembolic strokes as compared to thromboembolic [11]. This type of thrombus has a greater affinity for rtPA, and responds better to thrombolytic

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http://dx.doi.org/10.1016/j.advms.2017.08.003
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treatment [4]. Another possibility is that the observed improvement in functional outcome is due to genetic variability of fibrinolysis inhibitors [5], the neuroprotective effect of exposure to ovarian estrogens [4], and an increased rate of arterial recanalization in women following administration of rtPA [12]. However, studies have also shown that the difference in outcome observed between genders after treatment with rtPA is relatively small [13–16]. The complexity of this issue has also been increased by another study that found that men are three times more likely to have a good functional outcome with rtPA treatment following an acute ischemic stroke [17]. Moreover, the observed gender differences have been attributed to demographic factors such as age [1,2,4,18], comorbidity [2], pre-stroke functional status [2,4], and stroke severity [5,11,18]. Differences in methods and timing of hospital presentation [1,2] and robustness of hospital evaluation [16] may also play a role. Overall, women are less likely than men to receive rtPA treatment [4,18,19].

Therefore it is tempting to speculate that thrombolysis maybe beneficial more to women than to men, as shown by some studies [1,6,7]. One possibility is that the observed difference could be that clinical risk factors associated with thrombolysis efficacy are not present in the same proportions among women presenting with stroke than among men. Our first objective is to identify the different risk factors in rtPA treated population and determine whether these risk factors are different between male and female populations. Since male and female do not present the same exclusion criteria in the general population, our second objective is to determine the effect of gender in the exclusion criteria for rtPA using a prospective registry of data of ischemic stroke patients admitted between 2010 and 2013 to a primary stroke center. We

Table 1
The baseline demographic and clinical characteristics of patients who received rtPA vs. those who did not.

Characteristic	rtPA (N = 241)	No rtPA (N = 422)	p-value
Patient Age in Years:			
Mean ± SD	66.9 ± 14.3	69.6 ± 15.0	0.021*
Range	28, 96	27, 97	
Age Group: No. (%)			
<50 years	31 (12.9)	46 (10.9)	0.087
50–59	41 (17.0)	64 (15.2)	
60–69	61 (25.3)	78 (18.5)	
70–79	55 (22.8)	109 (25.8)	
≥80	53 (22.0)	125 (29.6)	
Gender: No. (%)			
Female	119 (49.4)	235 (55.7)	0.117
Male	122 (50.6)	187 (44.3)	
Race: No. (%)			
Caucasian	199 (82.6)	333 (78.9)	0.495
African-American	39 (16.2)	84 (19.9)	
Other	3 (1.2)	5 (1.2)	
Hispanic Ethnicity: No. (%)	4 (1.7)	6 (1.4)	0.809
Body Mass Index:			
Mean ± SD	28.0 ± 6.6	28.4 ± 7.6	0.547
Range	13, 54	11, 75	
Medical History: No. (%)			
Atrial Fib/Flutter	49 (20.3)	99 (23.5)	0.352
CAD (Coronary Artery Dz)	72 (29.9)	134 (31.8)	0.615
Carotid Stenosis	5 (2.1)	23 (5.5)	0.038*
Diabetes	59 (24.5)	129 (30.6)	0.094
Dyslipidemia	119 (49.4)	208 (49.3)	0.983
CHF	20 (8.7)	62 (14.7)	0.016*
Hypertension	191 (79.3)	326 (77.3)	0.550
Previous Stroke	45 (18.7)	123 (29.1)	0.003*
Previous TIA	28 (11.6)	55 (13.0)	0.596
Peripheral Vascular Dz (PVD)	14 (5.8)	17 (4.0)	0.296
Smoking history	81 (33.6)	100 (23.7)	0.006*
Initial NIH Stroke Scale (Actual):			
Mean ± SD	10.7 ± 6.5	8.1 ± 6.9	<0.001*
Range	0, 25	0, 25	
Initial NIH Stroke Scale Group: No. (%)			
0–9	125 (51.9)	274 (64.9)	0.002*
10–14	51 (21.2)	54 (12.8)	
15–20	37 (15.4)	64 (15.2)	
20–25	28 (11.6)	30 (7.1)	
Risk of Mortality GWTG Ischemic Stroke:			
Mean ± SD	6.47 ± 6.3	5.53 ± 5.6	0.057
Range	0.7, 35.6	0.4, 36.4	

* $P < 0.05$.

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