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Assessment of risk factors, cost of treatment, and therapy outcome in stroke patients: evidence from cross-sectional study

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ABSTRACT

Introduction: Objectives of this study were to assess risk factors, cost of treatment, and therapy outcomes in stroke patients.

Methods: This cross-sectional study was conducted in 130 patients of either sex at a government tertiary care hospital of India. Relevant information was collected from available records and through patient interview after permission from the ethics committee. National Institute of Health Stroke Score (NIHSS) was used to assess therapy outcome. Analysis of variance and the students t-test were applied appropriately where needed.

Results: Higher body mass index, sedentary lifestyle, tobacco use, and elevated systolic blood pressure were observed as risk factors in participants. The mean cost of stroke treatment observed at this hospital was Indian Rupee 17,934.71 (\notin 218.70; USD 267.67). The direct medical cost was the principal component in stroke treatment that ranged from 6% to 27% of the average six-month salary of patients in different socioeconomic classes. A significant improvement (p < 0.05) in health outcome (NIHSS Score) was observed in participants after treatment.

Conclusion: The data on the cost of stroke treatment from this study may be used for further pharma-coeconomic studies.

1. Introduction

Non-Communicable Diseases (NCDs) were responsible for 38 million global deaths according to the World Health Organization's (WHO) 2012 report. About 28 million [1] deaths occurred in Lowand Middle-Income Countries (LMICs) and 48% of them were before the age of 70 [2]. Stroke is considered as one of the major causes of mortality and physical disability among NCDs [3,4]. Prevalence, mortality, and socioeconomic burden of stroke are increasing concern globally and are becoming more alarming in LMICs. The incidences of stroke in LMICs increased to more than double in the past four decades [5-9]. World Bank has classified India under the category of LMICs [10]. The prevalence of stroke in India varies from 42.29 to 559 per 100,000 population as reported in a recently published systematic review [11]. The existence of diversity in socioeconomic classes, cultures, lifestyles, food habits in rural, urban, and metropolitan regions of India was identified as the underlying cause for this large variation. As per Government estimates, about 22% of the population of India is below the poverty line [12]. The concept of health insurance is not much prevailing in India and access to the insurance facility is limited to public sector employees and to a selected population who can afford its premium [13]. As a matter of fact, most of the patients in India bear the healthcare expenditures from their own pocket [14]. Limited information is available about health-care expenditure in India due to stroke. Currently, most available data on stroke treatment cost are from other countries [15-17]. Costs of stroke are variable in LMICs because of prevailing heterogeneous health-care systems (government and private). Kwatra et al. conducted a study in 2013 at a private hospital of northwest India to analyze the cost of illness in stroke patients [18]. Few studies were conducted on the socioeconomic burden of stroke in an Indian population [19,20]. Information on stroke treatment cost in India is mostly available from studies conducted at private hospitals. Keeping the above in view, the primary objective of this cross-sectional study was to analyze the cost of stroke treatment at government hospital and then compare it with cost reported by Kwatra et al. [18] at a private hospital of the same region.

Stroke is reported more predominantly in male gender and persons with high BMI, hypertension, diabetes, and poor psychosocial status [21,22]. The secondary objective of the study was to investigate the risk factors of stroke in enrolled patients. Attempts were also made to assess stroke therapy outcome in patients using the National Institute of Health Stroke Scale (NIHSS) [23]. The results are expected to be used for future pharmacoeconomic analysis about stroke treatment cost in the heterogeneous health-care system of India.

2. Methodology

This study was conducted at a neurology department of a tertiary care government hospital of Punjab, India. Patients of age 18 years or above, willing to give informed consent and had confirmed the diagnosis of stroke as per WHO stroke definition, were included in

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Article highlights

- Stroke is considered as one of the major causes of mortality, physical disability, and financial burden on patients and their families.
- This was a cross-sectional study conducted at a government hospital to address risk factors, cost of illness, and outcome of therapy.
- We included 130 patients in the final analysis, the total mean cost for treating patients hospitalized due to stroke (for 6 months from the date of admission) was found to be INR 17,934.71; € 218.70; USD 267.67. Direct medical cost was INR 10,310.28; € 125.73; USD 153.88 while direct non-medical cost was found to be INR 2699; € 32.91; USD 40.28. Indirect cost of stroke treatment was found to be INR 4924; €60.04; USD 73.
- Mean systolic blood pressure (p< 0.05) in the female was significantly higher as compared to male participants.
- A slight increase in the score at 3 months (compared to baseline score at the time of hospitalization) was observed in male (43.29%) as compared to female (40.93%) participants.
- Current study failed to include patients who received mechanical thrombectomy, as this treatment facility was not available at the studied hospital.

the study. Patients with multiple chronic diseases like severe osteoarthritis of hip or knee were excluded from the study. According to inclusion criteria, relevant details of 130 patients (out of 150 selected patients) collected through interview and medical records or bills. Ten patients did not provide inform consent form, while follow-up was not possible for the other 10 patients. The study was conducted for a period of 6 months (14 December 2017-20 May 2018). Direct medical cost for each patient was calculated by adding cost of medicines, surgical consumables, laboratory investigations, radiological investigations (CT scan and MRI) along with consultation and bed charges. Drug Index or Government of India's android mobile application (Pharma Sahi Daam) was used to calculate medicine cost. The maximum price was taken into consideration for the drug prescribed by generic name. The cost of medication prescribed on discharge was calculated for 6 months. Direct medical cost during hospitalization added with the cost of medicines prescribed at the time of discharge (calculated for 6 months) resulted in total direct medical cost occurred to patients for 6 months starting from the day of hospitalization. Cost of thrombolytic therapy was included in the direct medical cost. Mechanical thrombectomy cost could not be included due to non-availability of the facility at this hospital. The direct non-medical cost that calculated for each patient includes the cost of food during the hospital stay and travel expenses. Indirect cost calculated as the loss of productivity of patient and caregivers by multiplication of average daily wages and the number of days of hospitalization. Intangible cost and opportunity cost excluded from the study as were difficult to assess. Mean total cost of treating a stroke patient in this study included direct medical cost, direct non-medical cost, and indirect cost.

Surveillance of risk factors of the stroke was performed using WHO STEPwise approach. Patients having a medical history of depression and/or taking antidepressant medicines were categorized under the depression condition. Patients were categorized in the upper or upper middle or lower middle or upper lower or lower class according to the Modified Kuppuswamy's scale based on education, occupation, and income [24]. The National Institute

of Health Stroke Scale was used to assess clinical condition and therapy outcome in enrolled patients. Statistical analysis of data was performed using IBM SPSS Statistics Version 16. Analyzed data were presented in the form of mean with standard deviation or number or percentage as applicable. Analysis of variance and student t-test applied to analyze differences between means of independent categorical variables and the dependent continuous variables. One sample t-test was used to compare the results of this study (mean total direct medical cost) with reported mean direct medical cost for 6 months in stroke patients at tertiary care private hospital [18]. A p value \leq 0.05 was considered as significant. Equivalent cost in international currency taken in this study as 1 INR equal to 0.012 Euro and 1 INR equal to 0.014 US Dollar (as on 10 October 2018).

2.1. Ethical approval

Approval for the study was obtained from the institutional ethics committee wide protocol no. ISFCP/IEC/2017/109. Informed consent obtained from each participant patient/caregiver and study conducted in accordance with standards prescribed by the ethics committee.

3. Results

3.1. Socio-demographic profile of patients

A total of 130 patients (out of 150) were included in the study with a response rate of 86.6%. Among all included participants (N = 130) 61.5% were male patients. A major proportion of patients (66.9%) were below 60 years of age and observed mean age was 55.62 years. Equal numbers of participants in the study belonged to rural and urban areas. Socio-demographic profile and economic class categorization of patients are shown in Table 1. A large proportion of patients in this study (70.8%) were either overweight or obese. More than half of stroke patients (56.15%) had a history of depression. Majority of patients (80.8%) had comorbid health conditions like hypertension (39.2%) or diabetes mellitus (3.8%), or both 20 (15.3%).

3.2. Cost components involved in treating stroke patients

The total mean cost for treating stroke patient was Indian Rupee (INR) 17,934.71 (\notin 218.70; USD 267.67). Observed direct medical cost was INR 10,310.28 (\notin 125.73; USD 153.88), while direct non-medical cost was INR 2699 (\notin 32.91; USD 40.28). The indirect cost of stroke treatment was found as INR 4924 (\notin 60.04; USD 73) in this study. Components of health care cost are described in Table 2. It was observed that direct medical cost (57.48%) was the major cost causing component that followed by indirect medical cost (27.46%) and direct non-medical cost (15.6%).

Results of the study revealed that lower economic class patients spent a substantial amount (27.64% of their average salary of 6 months) as out-of-pocket expenditure that followed by upper lower and lower middle class. The upper middle and upper class of patients spent 7.78% and 6.04% of the average salary in 6 months due to illness. The data are described in Table 3.

Tak	ole	1.	Profile	of	patients	participated	in	the	study.
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Characteristics	n(%)	Characteristics	n (%)
Male	80 (61.5)	Under weight/normal	38 (29.2)
Female	50 (38.5)	Overweight/nbese	92 (70.8)
<60	87 (66.9)	No co-morbidity	25 (19.2)
>60	43 (33.1)	Hypertension/diabetes/both	105 (80.8)
Non-addict	69 (53.1)	Upper socioeconomic class	14 (10.8)
Alcoholic/smoker/substance abuse	61 (46.9)	Upper middle socioeconomic class	38 (29.2)
Rural	65 (50)	Middle socioeconomic class	34 (26.2)
Urban	65 (50)	Upper lower socioeconomic class	31 (23.8)
History of depression Yes	73 (56.15)	Lower socioeconomic class	13 (10)
History of depression No	57 (43.84)		

Table 2. Cost components included in calculating total cost during the stay at the hospital.

Type of cost	Average cost	Percentage of total cost
Direct medical cost	INR 10,310.28; USD 153.88;€ 125.73	57.48%
Indirect cost	INR 4924.92; USD 73; €60.04	27.46%
Direct non-medical cost	INR 2699.50; USD 40.28; € 32.91	15.6%
Total cost	INR 17,934.71; USD 267.67; € 218.70	100%

The total mean cost was calculated by adding all cost components for categories as described in Table 4. It was observed that the total cost of treatment during a hospital stay was significantly higher (p < 0.05) in patients greater than 60 years of age. There was a significant difference (p < 0.05) observed in the cost of treatment during the hospital stay in upper middle class as compared to lower socioeconomic class. The cost of treatment was significantly higher (p < 0.05) in patients who addicted to tobacco (smoking or chewable tobacco) or alcohol or both or drug abuse.

3.3. Risk factors and outcome

To assess the association of mean age, body mass index, systolic blood pressure, duration of hospital stay, and the total cost with respect to gender, paired t-test was applied considering female and male participants as groups. Mean systolic blood pressure in the female was significantly higher (p < 0.05) as compared to male patients. The difference in mean age or BMI or hospital stay or total cost, however, was non-significant. NIHSS score was calculated in both genders at the time of admission and after three months to assess the outcome of therapy. Paired t-test applied to compare baseline score (at time of admission) with the score after 3 months. A significant improvement in the score was observed in both genders. A slight increase in the score at 3 months (compared to baseline score) was observed in male (43.29%) as compared to female (40.93%) participants. The presence of depression state was observed in 58% female and 55% of the male patients. A major proportion of female patients (68%) had a sedentary lifestyle, while it was observed as 36.3% in the male stroke patients. Ischemic type of stroke prevailed more in both genders (82.5% of the male and 74% of the female patients) than hemorrhagic stroke (Table 4).

4. Discussion

This observational study was conducted with an objective to assess health-care cost, prevalence of risk factors that developed stroke and outcome of drug therapy in enrolled

participants at a tertiary care government hospital. A major proportion (about two-third) of enrolled patients were below 60 years of age which is considered a productive age. This leads to a poor impact on the socioeconomic status of families of patients and increases the healthcare cost burden on the economy of a country. The prevalence of stroke observed in male patients was higher as compared to females. Alcohol or smoking or substance abuse addicts (n = 61) were 46.9% of the total patient (N = 130). Tobacco users were in majority (68.8%) among addict patients. Smoking is considered as the major risk factor for cardiovascular events and may aggravate the illness. Cost of treatment was significantly lower in non-addicts as compared to addicts (Table 4). History of depression was observed in more than half of the patients (56.15%) that indicates the correlation between depression and stroke prevalence. Over 70% of the studied participants were in either overweight or obese category as calculated by BMI. It is believed that increased weight is a risk factor for stroke occurrence, and the findings of our studies are in concordance. Co-morbidity of stroke with either hypertension or diabetes or both prevailed in over 80% participants. More than half of patients in this study were from the upper middle or middle-class socioeconomic class as per modified Kuppuswamy's scale. The direct medical cost was the principal component (57.48%) of total cost due to stroke that followed by indirect medical cost and direct non-medical cost.

Result of cost analysis (one sample t-test) revealed that total direct medical cost in all socioeconomic classes was significantly lower (p < 0.05) at this government hospital as compared to the direct medical cost reported in a study (INR 52,555;\$ 784.40; €640.91) conducted by Kwatra et al. in Punjab region at a private hospital [19]. Our study results are in concordance with a report of the national survey on social consumption related to health that was conducted by an agency of the government of India in the year 2014. The report stated the fact that average expenditure for hospitalized treatment from a public (government) sector hospital was much lower than that from a private sector hospital in both rural and urban areas [25]. Significant (p < 0.05) higher mean hospital stay (13 days) in a private hospital as compared to the government hospital (6.81 days) seems one of the reasons behind this observation. As the hospital stay increases, the cost of treatment also increases. Another reason could be the availability of medicines and the cost of laboratory investigations at a very subsidized rate in this study at a government hospital as compared to the private hospital.

Table 3	. Cost of illness in	stroke patients	of various economic	groups.						
		Duration of					Direct medical	Baseline NIHSS at		
	Socioeconomic	stay in days	Direct medical cost	Direct medical cost during	Total direct medical cost		cost as % of	time of	NIHSS (After	%
S. No.	class	(Mean ± SD)	in 6 months (a)	stay at hospital (b)	occurred in 6 months (a + b)	Average salary of 6 months	salary	admission	3 months)	Improvement
-	Upper	$7.64 \pm 0.65^{###}$	INR4480 ± 538	INR12459 ± 3628	$INR16,939 \pm 4166^{***}$	INR264000 (\$39	940.36;063219.51)	6.79 ± 3.46	$4.14 \pm 2.68^{\circ}$	39.02%
			(\$66.86; €54.63)	(\$185.95; €151.93)	(\$252.8; €206.577)					
2	Upper middle	$6.21 \pm 0.32^{###}$	$INR4394 \pm 618$	$INR10959 \pm 1710$	$INR15,353 \pm 2328^{***}$	INR197268 (\$2944.29; €2405.7)	7.78%	6.18 ± 3.98	$3.61 \pm 2.98^{\circ}$	41.58%
			(\$65.58; €53.58)	(\$163.57; €133.64)	(\$229.15; €187.23)					
m	Lower middle	$7.09 \pm 0.32^{###}$	INR4433 ± 738	$INR9065 \pm 719$	$INR13,498 \pm 1457^{***}$	INR131190 (\$1958	8.05; €11529.87)	9.38 ± 7.27	$5.47 \pm 4.42^{\circ}$	41.68%
			(\$66.16; €54.06)	(\$135.2985;€110.5488)	(\$201.46; €164.60)					
4	Upper lower	$6.84 \pm 0.49^{###}$	INR3604 \pm 663	INR9430 \pm 897	INR13,034 \pm 1560***	INR76608 (\$11 ²	43.40; 16904.24)	10.87 ± 7.08	$6.42 \pm 4.73^{\circ}$	40.93%
			(\$53.79; €43.95)	(\$140.7463;€115)	(\$194.53; €158.95)					
5	Lower	$6.31 \pm 0.99^{\#\#}$	INR3391 ± 374	INR6787 ± 598	INR10,178 \pm 972***	INR36822 (\$549.58; €449.04)	27.64	10.23 ± 7.90	$5.08 \pm 4.75^{\circ}$	50.23%
			(\$50.61; €41.35)	(\$101.2985; €2.76829)	(\$151.91; €124.12)					
# One s	ample t-test, com	pared mean stay	y of all classes with te medical cost with te	test value 13 days $p < 0.001$	lin reference (Kwatra et al)					

Equivalence of Indian Rupee to international currency (1 INR=0.012 Euro, 1 INR=0.014 US Dollar)

^Paired sample t-test for in class for NIHSS score calculated at baseline and at 3 months from discharge

mentioned in the table is in Indian Rupee (INR), US Dollar (\$), and Euro (\in).

Cost

Table 4. Total mean cost occurred with reference to age group, socioeconomic class, and social history of addiction during the stay at the hospital.

Categories	Total mean cost \pm SD during hospital stay	p Value
Age (y)		
<60 or 60 years	17,485 ± 8993 (\$260.97; €213.23)	<0.05
>60	19,768 ± 10,337 [^] (\$295.04; €241.07)	
Socioeconomic class		
Upper	26,209 ± 3628* (\$391.17; €319.62)	<0.001
Upper middle	20,038 ± 2095* (\$299.07; €244.36)	
Lower middle	16,961 ± 752 (\$253.14; €206.84)	
Upper lower	15,531 ± 915 (\$231.80; €189.40)	
Lower	14,211 ± 814 (\$212.10; €173.30)	
Social history		
Non-addict	15,162 ± 8354 [#] (\$226.29; €184.90)	<0.05
Addict	21,853 ± 12,228 (\$326.16; €266.5)	

^indicated that value is significant (p < 0.05) as determined by paired t-test between the group of age 60 or less than 60 years and greater than 60 years. *indicates that values are significant (p < 0.001) as determined by applying one way ANOVA. Compare with values for the lower socioeconomic class.

#indicates value is significant (p < 0.05) as determined by paired t-test between group of non-addicts and addicts.

Health insurance is not very common in India and the majority of people pay out-of-pocket expenditure for healthcare needs that adversely affect their socioeconomic conditions [26]. The mean direct medical cost occurred in 6 months due to hospitalization and follow-up treatment for stroke in the present study for upper, upper middle, lower middle, upper lower, and lower class was INR 16939, 15353, 13498, 13034, and 10178, respectively. This out-of-pocket expenditure was 6.04%, 7.78%, 10.28%, 17.01%, and 27.64% of the average 6-month salary of above-mentioned classes, respectively, from upper to lower class. These data indicated that out-of-pocket expense due to hospitalization followed by stroke occurrence was a significant economic burden on all the classes. It was highest on the lower class and least on upper-class participants of this study.

The outcome of treatment was accessed using NIHSS scoring. This score calculated in patients of all classes at the time of admission and at follow-up after 3 months. A significant improvement observed in quality of life and ability to do the day to day work in all patients as compared to baseline condition which was calculated at the time of admission. Percentage of improvement in NIHSS score at 3 months was 39.02%, 41.58%, 41.68%, 40.93%, and 50.23% for upper, upper middle, lower middle, upper lower, and lower class, respectively. This gives an estimate that the treatment given at a government tertiary care hospital is effective at significantly lower direct medical cost (Table 3).

The total mean cost occurred during the hospital stay in patients aged above 60 years was significantly higher (p < 0.05) than in patients below or equal to 60 years of age. This might be due to associated co-morbid conditions. The mean total cost occurred during hospital stay was significantly higher in the upper and upper middle class as compared to the cost occurring in the lower class. The cost occurrence in addicts (tobacco and alcohol users) was significantly higher as compared to that in non-addicts. The reason might be worsening of the condition due to the harmful effects of tobacco and alcohol consumption over the period of time (Table 4). It is important to learn that appropriate patient counseling on modifiable risk factors like smoking cessation, avoiding alcohol consumption and weight

reduction may reduce incidences/recurrences of the stroke and out-of-pocket health-care expenditure.

Prevalence of parameters like mean age, mean body mass index, blood pressure, duration of stay, total cost, NIHSS scoring, history of depression, physical activity, and type of stroke were investigated with reference to gender (Table 5). It was observed that there was no significant gender-specific difference with respect to all parameters as mentioned above except systolic blood pressure. Systolic blood pressure was higher in female patients as compared to males. Overall significant improvement in health-care status was observed in both genders. Significant improvement (p < 0.05) in NIHSS after drug therapy was observed in both female (40.93% of the baseline score) and male (43.29% of the baseline score) patients. The results of our study are in concordance with findings reported elsewhere in the literature that women are having a high prevalence rate of stroke due to increased life expectancy. However, current literature on differences in the stroke prevalence between the sexes is conflicting [27–30]. Women are having higher incidences of stroke in the later age >86 years, while in our study the average age in female was much less (57.10 years). The cited study was conducted in Copenhagen where life expectancy is more as compared to India.

In our study, the mean systolic blood pressure (SBP) was higher in the female as compared to the male. Increase in SBP is a known risk factor for precipitation of stroke both in male and female, and the results of the present study are also in concordance with this fact [27]. According to a study, sex differences in stroke patients do in fact exist. This study reports that women are older at the stroke onset with higher severity and have a worse functional outcome as compared to men [31]. In our study also, the similar results were found, though could not reach the level of significance.

Table 5. Compariso	on of different	parameters	assessed in	n female	and male	study
participants.						

Parameter assessed	Female ($N = 50$)	Male ($N = 80$)
Mean age	57.10 ± 13.35	54.69 ± 12.34
Mean body mass index	28.925 ± 5.35	27.11 ± 4.21
Systolic blood pressure	167.84 ± 24.257*	147.56 ± 27.049
Hospital stay duration	7.00 ± 2.665	6.60 ± 2.231
Total cost	18,695.20 ± 9210.498	17,956.75 ± 9691.701
NIHSS score		
Baseline (at time of admission)	9.38 ± 6.353	8.13 ± 6.377
After 3 months	$5.54 \pm 4.381^{\#}$	$4.61 \pm 4.394^{\#}$
% Improvement	40.93	43.29
(Difference between		
score at baseline and		
after 3 months		
divided by baseline		
score and multiplied		
with 100)		
History of depression		
No	42.0	45.0
Yes	58.0	55.0
Physical activity		
Sedentary	68.0	36.3
Moderate	20.0	45.0
Heavy	12.0	18.8
Type of stroke		
lschemic stroke	74.0	82.5
Hemorrhagic stroke	26.0	17.5

* p<0.05 as determined by paired t-test between male and female group for systolic blood pressure.

p<0.05 as determined by paired t-test in male and female groups separately for NIHSS score taken at baseline (at time of admission) and after 3 months.

4.1. Limitations

The current Study has its own limitations; it was conducted only at one government hospital. The cost of treating stroke patients cannot be generalized to all hospitals of India as the cost of treatment is higher in case of a private hospital and sample size of the study was small (n = 130). Moreover, we could not include patients who received mechanical thrombectomy, as this treatment facility was not available at the studied hospital.

5. Conclusions

From this evidence-based study, it may be concluded that stroke incidence is associated with risk factors like tobacco and alcohol consumption, depression, increased blood pressure, lesser physical activity, and increased BMI. The total mean cost for treatment of stroke during and after hospitalization (6 months) in patients was found INR 17,934.71; € 218.70; USD 267.67. Direct medical cost observed as INR 10,310.28 (€ 125.73; USD 153.88), while direct non-medical cost was INR 2,699 9 (€ 32.91; USD 40.28). Indirect cost was INR 4924; €60.04; USD 73. The results of the present study suggest that the cost of treatment in stroke patients at India is significantly less at government hospitals as compared to a private hospital. The patients had to bear out-ofpocket expenditure on treatment that ranged from 6% to 27% of their average salary in different socioeconomic classes. The treatment given at a government tertiary care hospital is effective at significantly lower direct medical cost.

This study provides evidence about the cost for treating stroke patients during and after hospitalization (for total six months duration from the date of admission up to six months) and can be used for further pharmacoeconomic modeling and research on stroke.

Author contributions

M Chhabra and M S Rathore conducted literature review, contributed in study design and data collection and draft preparation of manuscript. A Sharma helped in data analysis, A K Rathore helped in reviewing the paper and provided assistance in interpretation of data. All authors approve this version of manuscript and agree to be accountable for all aspects of the work.

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Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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