

# Prevalence of primary and secondary subfertility and its associated factors in Regional Director of Health Services area in Colombo district Sri Lanka: A community-based cross-sectional study

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(Key words: primary subfertility, secondary subfertility, prevalence, associated factors, Sri Lanka)

## Abstract

**Introduction:** Subfertility is a major life issue that affects the quality of life. Most of them are residing in developing countries. The prevalence of subfertility is an essential element to identify the magnitude of the problem in each country.

**Objective:** To assess the prevalence of primary and secondary subfertility and its associated factors in the Colombo district, Sri Lanka.

**Methodology:** This cross-sectional study used a stratified cluster sampling method to recruit 3104 married women aged between 15-49 in 38 urban and rural clusters in the Colombo district, Sri Lanka. The study was conducted in 2018-19 and used a structured questionnaire based on the clinical definition of subfertility.

**Results:** The point prevalence of primary subfertility was 6.08 (95% CI:5.3-7.0). A significantly high prevalence of primary subfertility was reported among female partners with tertiary education (aOR:2.80; 95% CI:1.08-7.39) compared to primary or no education and employed women (aOR:1.88; 95% CI:1.37-2.57) compared to unemployed women. The point prevalence of secondary subfertility was 8.40 (95% CI:7.4-9.4). A significantly high prevalence of secondary subfertility was reported among female partners with tertiary education (aOR:2.55; 95% CI:1.16-5.59) compared to primary or no education, unemployed women (aOR:1.65; 95% CI:1.25-2.19) compared to employed women and women of other ethnic groups (aOR:1.97; 95% CI:1.13-3.32) compared to Moor ethnic group.

**Conclusion:** The prevalence of both primary and secondary subfertility was 14.5% (95% CI:13.3-15.7) among the married women aged between 15-49 years in the Colombo Regional Director of Health Services area. The development of effective and rational public health policies for the prevention of subfertility and increased availability of advance reproductive technology facilities should be considered.

## Introduction

Subfertility is a serious health issue and it affects the quality of life of married couples. In low-and-middle-income countries having a child is a factor that lends more societal recognition to a woman compared to that in high-income countries. Bearing a child seems to enhance women's status in the community in low and middle-income countries. Pregnancy and motherhood are highly esteemed in Asian cultures [1-3].

The World Health Organization, jointly with the International Committee for Monitoring Assisted Reproductive Technologies (ICMART) and its other partners developed a clinical definition for subfertility. The International Classification of Diseases (ICD) 10 also uses this definition [4-6]. The present research used the clinical definition of primary and secondary subfertility to assess the prevalence. The clinical definition of primary subfertility is "when a woman has never conceived despite cohabitation and regular unprotected sexual intercourse for twelve months" [7,8]. Secondary subfertility is defined

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as a “delay for a couple to conceive again, who have conceived previously, even if the pregnancy may not have been successful due to miscarriage, ectopic pregnancy, etc. [8].

Twenty-five population surveys revealed that 12-month prevalence rate of subfertility ranged from 3.5% to 16.7% in more developed countries and from 6.9% to 9.3% in less developed countries [9]. A study that assessed the burden of infertility in 195 countries revealed globally, the age-standardized prevalence rate of infertility increased by 0.370% per year for females and 0.291% per year for males from 1990 to 2017 [10].

In Sri Lanka, only a few community-based studies have been conducted to assess the prevalence of subfertility. The prevalence of primary and secondary subfertility was 5.52% and 10.07% respectively in a community-based study in the Colombo district in 2006 [11]. Another community-based study that was carried out in 1994 estimated a prevalence rate of 4.1% and 16.0% in the Colombo district respectively for primary and secondary subfertility [7]. The high prevalence of subfertility during the past 20 years is reflected in these data. The rate of secondary subfertility is increasing. To ascertain the real prevalence of subfertility in Sri Lanka, fresh prevalence research was required.

According to the WHO disability categorization, subfertility ranks as 5<sup>th</sup> highest serious global disability among the population under the age of 60 years [12]. Prevalence is an essential element to identify the severity of the situation in each country. The prevalence rate will help to understand the magnitude of the problem to higher authorities and future funds allocations for the improvement of subfertility management facilities including assisted reproductive technology (ART) [13].

There are several correctable risk factors that lead to subfertility, such as overweight, advanced maternal age, sexually transmitted diseases etc., which could be prevented through proper education and counselling and early referral at the field level. Considering the financial constraints incurred by low and middle-income countries, preventive measures would undoubtedly be the most cost-effective strategy to follow [14, 15]. In Sri Lanka, public health midwives (PHM) would be the primary care providers with whom the sub-fertile couple would initially meet. These primary care providers could play a critical role in improving their knowledge and understanding of their problems and advising them appropriately. However, the identification of the sub-fertile couples from the PHMM to provide care at the field level was very low. The information fed to the official Reproductive Health Management Information System (RHMISS) from the MOHs indicates Colombo district subfertility prevalence was 4.6% in 2020 [16], which was far below the research evidence

from Lansakkara, 2006. Therefore, the present research was conducted to get accurate evidence of the current prevalence of subfertility.

The objective of the present study was to assess the prevalence of primary and secondary subfertility and find out its associated factors.

## Methodology

This cross-sectional study was carried out from October 2018 to February 2019 in the Colombo district's Regional Director of Health Services (RDHS) area. Sri Lanka is divided into 25 administrative districts, and this was carried out in the Colombo district which has the highest population density. Each health district is subdivided into medical officer of health (MOH) areas and the Colombo RDHS area has 18 MOH areas. Each MOH area consists of several service areas that are catered by a public health midwife (PHM).

The study unit was married couples whose female partner was in the age range of 15-49 years and residing in the Colombo RDHS area. Couples, whose permanent residence was outside the Colombo RDHS area and residing in temporally for less than six months were excluded from the study.

For the calculation of the sample size, the expected prevalence of subfertility was taken as 15.0 %, based on the most recent study done by Lansakkara, *et al.* in 2006 in Colombo Regional Director of Health area and the required level of precision taken as 4%. A design effect of 9.9% and 10% of non-response rate was added resulting in a required sample size of 3366. The design effect was calculated based on the following formula. Deff (design effect) =  $1 + (b - 1) p$ .  $b$  = average number of responses received per cluster (cluster size). In this study cluster size was taken as 90.  $p$  = rate of homogeneity (roh), a measure of the variability between clusters as compared to the variation within clusters. In this study,  $p$  was taken as 0.1.  $Deff = 1 + (90 - 1) 0.1$ .  $Deff = 9.9$

A two-stage stratified cluster sampling technique with a probability proportionate to the registered married couples with PHMs in urban and rural areas was used to select the sample. The public health midwife (PHM) area was selected as the primary sampling unit (clusters). Two lists of PHM areas (clusters) with the number of couples were prepared for urban and rural areas separately. Thirty-eight (29 urban and 9 rural) clusters were selected by applying the random sampling method separately for urban and rural populations. Each cluster consisted of ninety eligible couples. After selecting the clusters (PHM areas), a list of all the eligible families in that PHM area was prepared with the help of the public health midwife (PHM). Two months were given to the PHM to update the eligible

couple registry in that area. Thereafter, an eligible couple in each selected cluster was chosen randomly. That eligible couple was selected as the first couple in that cluster. Then the next eligible couple on the list was selected. Likewise, consecutive sampling was done until 90 eligible couples were selected.

A team of experts, including two consultants in obstetrics and gynaecology and two public health physicians prepared the questionnaire to identify the primary and secondary sub-fertile couples. It was pre-tested with 20 sub-fertile couples and modified. Content validity was ensured with expert opinion.

Data collection was conducted by public health nursing sisters (PHNS), in each MOH area. The PHNS is a supervisory officer, who supervises the field staff in the MOH units. The questionnaire was administered to the female partner of the couple as a face-to-face interviewer administered method.

Ethics clearance was granted by the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka (Ref No: P/282/12/2017). Informed written consent was obtained from each participant prior to data collection.

The prevalence of primary and secondary subfertility is presented as proportions with confidence intervals according to the age category, ethnicity, religion, educational level, and urban and rural sectors. Multiple logistic regression was performed on both primary and secondary sub-fertile couples separately to see the association between selected socio-demographic factors of the female partner, such as age, employment status, education level, ethnicity, and family monthly income.

## Results

Out of the recruited sample, 3104 female partners of married couples responded resulting in a 92.2% respondent rate. The highest percentage (21.7%) of women in the

study population belonged to the age category of 30-34 years. Most of the women in the sample were unemployed (61.2%) and the highest education level of most of the study participants was grade 6-10 (36.6%).

The point prevalence of primary subfertility was 6.08% (95% CI: 5.3-7.0). The prevalence of primary subfertility was highest and equal among couples whose female partners were between 25-29 and 30-34 years age range (7.7% each). The lowest prevalence of primary subfertility was reported in the Muslim ethnicity (4.1%). Primary subfertility prevalence increases with the education levels of both male and female partners. The highest prevalence of primary subfertility was reported within the couples whose male (10.3%) and female (9.6%) partners with tertiary education (Table 1).

The point prevalence of secondary subfertility was 8.40% (95% CI: 7.4-9.4). The prevalence of secondary subfertility was highest (14.1%) among couples whose female partners were between 35-39 age group. The highest prevalence of secondary subfertility was reported among couples with whose male (12.1%) and female (10.1%) partners with tertiary education and couples with unemployed (11.9%) male partners (Table 2).

A significantly higher prevalence of primary ( $p<0.05$ ) and secondary ( $P<0.05$ ) subfertility was reported in couples with female partners between 26 to 35 years of age compared to those below 25 years of age and female partners who were educated up to tertiary level compared to those with no or primary education. A significantly high prevalence of primary subfertility was reported with couples whose female partners were employed compared to unemployed ( $p<0.05$ ) and in secondary subfertility unemployed female partners had a high prevalence ( $p<0.05$ ) compared to employed female partners. A significantly lower level ( $p<0.05$ ) of the prevalence of secondary subfertility was reported among couples with female partners belonging to Moor ethnicity compared to other ethnic groups (Table 3 and 4).

**Table 1. Distribution of point prevalence of primary subfertility among married couples by selected socio demographic characteristics of female and male partners in cross-sectional study**

<i>Variable</i>	<i>Female partner</i>			<i>Male partner</i>		
	<i>Number of female partners interviewed (N= 3104)</i>	<i>Number of female partners belong to couples with primary subfertility</i>	<i>Prevalence (%) and 95% confidence interval</i>	<i>Number of male partners (N=3104)</i>	<i>Number of male partners belong to couples with primary subfertility</i>	<i>Prevalence (%) and 95% confidence interval</i>
<b>Age group</b>						
15-19	68	0	0.0	19	0	0.0%
20-24	395	16	4.1 (2.5-6.4)	202	4	2.0 (0.7-4.0)
25-29	622	48	7.7 (5.8-10.0)	512	24	4.7 (3.1-6.0)
30-34	675	52	7.7 (5.9-9.9)	633	46	7.3 (5.4-9.0)
35-39	561	42	7.5 (5.9-9.9)	646	52	8.0 (6.1-10.0)
40-44	407	18	4.2 (2.6-6.5)	515	36	7.0 (5.1-9.5)
45-49	376	13	3.5 (2.0-5.8)	392	20	5.1 (3.3-7.7)
>49	0	0		185	7	3.8 (1.8-7.6)
<b>Ethnicity</b>						
Sinhala	2462	157	6.4 (5.4-7.3)	2445	154	6.3 (5.3-7.2)
Tamil	316	18	5.7 (3.6-8.8)	328	21	6.4 (4.2-9.5)
Muslim	316	13	4.1 (2.4-6.9)	321	13	4.0 (2.4-6.8)
Other	10	01	10.0 (1.7-4.0)	9	1	11.1 (1.9-4.3)
<b>Religion</b>						
Buddhist	2300	142	6.1 (5.2-7.1)	2281	140	6.1(5.1-7.1)
Christian	190	19	10.0 (6.5-15.0)	207	19	9.2 (5.9-13.8)
Hindu	293	14	8.8 (2.9-7.9)	301	14	4.7 (2.7-7.6)
Islam	321	14	4.3 (2.5-7.1)	313	16	5.1 (3.1-8.1)
Other	0	0	0.0	2	0	0.0
<b>Level of education</b>						
No formal education	2	0	0.0	5	0	0.0
Passed grade 1-5	190	06	3.1 (1.4-6.7)	260	6	2.3 (1.0-4.9)
Passed grade 1-10	1138	44	3.8 (2.9-5.1)	1068	37	3.4 (2.9-4.7)
Passed G.C.E. (O/L) <sup>1</sup>	794	50	6.3 (4.8-8.2)	828	55	6.6 (6.2-9.8)
Passed G.C.E. (A/L) <sup>2</sup>	772	69	8.9 (7.1-11.1)	775	74	9.7 (7.9-12.1)
Tertiary education	208	20	9.6 (6.3-14.3)	164	17	10.3 (6.5-5.9)
<b>Employment</b>						
Employed	1239	106	8.5 (7.1-10.2)	2944	170	5.7 (4.9-6.6)
Unemployed	1865	83	4.4 (3.6-5.5)	160	19	11.9 (7.7-7.8)
<b>Sector</b>						
Rural	794	50	6.3 (4.8-8.2)	794	50	6.3 (4.8-8.2)
Urban	2310	138	6.0 (5.0-7.0)	2310	138	6.0 (5.0-7.0)

<sup>1</sup> General Certificate of Education (Ordinary Level)<sup>2</sup> General Certificate of Education (Advanced Level)

**Table 2. Distribution of point prevalence of secondary subfertility among married couples by selected socio-demographic characteristics of female and male partners in a cross-sectional study**

Variable	Female partner			Male partner		
	Number of female partners interviewed (N= 3104)	Number of female partners belong to couples with secondary subfertility	Prevalence (%) and 95% CI	Number of male partners	Number of male partners belong to couples with secondary subfertility	Prevalence (%) and 95% CI
<b>Age group</b>						
15-19	68	0	0.0	19	0	0.0%
20-24	395	14	3.5 (2.1-6.0)	202	10	4.9 (2.7-8.8)
25-29	622	41	6.6 (4.8-8.8)	512	30	5.8 (4.1-8.2)
30-34	675	74	11.0 (8.8-13.5)	633	53	8.3 (6.4-10.7)
35-39	561	78	14.1 (11.4-17.2)	646	69	10.6 (8.5-13.3)
40-44	407	41	10.1 (7.5-13.3)	515	67	13.0 (10.4-6.2)
45-49	376	13	3.5 (2.0-5.8)	392	23	5.8 (3.9-8.6)
>49				185	9	4.8 (2.5-8.9)
<b>Ethnicity</b>						
Sinhala	2462	215	8.8 (7.7-9.9)	2445	213	8.7 (7.6-9.8)
Tamil	316	30	9.5 (6.7-13.2)	328	33	10.7 (7.7-14.7)
Muslim	316	15	4.7 (2.9-7.6)	321	15	4.8 (2.9-7.8)
Other	10	01	10.0 (1.7-4.0)	9	1	11.1 (1.9-43.5)
<b>Religion</b>						
Buddhist	2300	204	8.8 (7.7-10.0)	2281	199	8.7 (7.7-9.9)
Christian	190	21	10.5 (6.9-16.0)	207	20	9.7 (6.3-14.4)
Hindu	293	20	8.2 (4.0-10.1)	301	27	8.9 (6.2-12.7)
Islam	321	16	4.7 (2.7-7.6)	313	16	5.1 (3.1-8.1)
Other	0	0	0.0	2	0	0.0
<b>Level of education</b>						
No formal education	2	0	0.0	5	0	0.0
Passed grade 1-5	190	11	5.8 (3.0-10.3)	260	20	7.7 (5.0-11.5)
Passed grade 1-10	1138	109	9.6 (8.0-11.4)	1068	69	6.5 (5.1-8.1)
Passed G.C.E. (O/L) <sup>1</sup>	794	57	7.2 (5.5-9.24)	828	79	9.5 (7.7-11.7)
Passed G.C.E. (A/L) <sup>2</sup>	772	65	8.4 (6.6-10.5)	775	78	10.6 (8.1-12.3)
Tertiary education	208	21	10.1 (6.7-14.9)	164	20	12.1 (8.6-18.0)
<b>Employment status</b>						
Employed	1206	86	7.1 (5.8-8.7)	2944	246	8.4 (7.4-9.4)
Unemployed	1898	175	9.3 (8.2-10.6)	160	16	10.0 (6.2-15.9)
<b>Sector</b>						
Rural	794	77	9.7 (7.8-11.9)	794	77	9.7 (7.8-11.9)
Urban	2310	184	8.0 (6.9-9.1)	2310	184	8.0 (6.9-9.1)

<sup>1</sup> General Certificate of Education (Ordinary Level)

<sup>2</sup> General Certificate of Education (Advanced Level)

**Table 3. Logistic multivariate regression analysis of factors associated with primary subfertility**

Characteristics	Unadjusted		Adjusted	
	<i>P</i> value	OR (95% CI)	<i>P</i> value	aOR (95% CI)
<b>Age (Female)</b>				
15-25	Ref			
26-35	0.002	2.33 (1.36-3.99)	0.019	1.94 (1.11-3.35)
>35	0.103	1.58 (0.91-2.75)	0.478	1.23 (0.69-2.17)
<b>Employment (Female)</b>				
Unemployed	Ref		Ref	
Employed	0.00	1.98 (1.47-2.67)	0.00	1.88 (1.37-2.57)
<b>Education level (Female)</b>				
No education or primary education	Ref		Ref	
Secondary education	0.112	1.95 (0.85-4.48)	0.220	1.68 (0.73-3.88)
Tertiary education	0.004	3.95 (1.54-10.18)	0.035	2.8 (1.08-7.39)
<b>Ethnicity (Female)</b>				
Muslim	Ref		Ref	
Other ethnic group	0.130	1.56 (0.87-2.77)	0.205	1.45 (0.82-2.59)
<b>Family income</b>				
<Rs. 35000	Ref		Ref	
Rs. 35000- Rs. 75000	0.216	1.33 (0.84-2.09)	0.310	1.27 (0.79-2.0)
>Rs. 75000	0.805	0.94 (0.59-1.57)	0.771	1.07 (0.66-1.73)

**Table 4. Logistic multivariate regression analysis of factors associated with secondary subfertility**

Characteristics	Unadjusted		Adjusted	
	<i>P</i> value	OR (95% CI)	<i>P</i> value	OR (95% CI)
<b>Age (Female)</b>				
15-24	Ref		Ref	
25-34	0.00	3.15 (1.78-5.54)	0.00	3.09 (1.74-5.48)
>35	0.00	3.49 (1.99-6.13)	0.00	3.72 (2.10-6.58)
<b>Employment (Female)</b>				
Unemployed	0.015	1.39 (1.07-1.83)	0.00	1.65 (1.25-2.19)
Employed	Ref		Ref	
<b>Education level (Female)</b>				
No education or primary education	Ref		Ref	
Secondary education	0.198	1.5 (0.80-2.80)	0.307	1.39 (0.73-2.16)
Tertiary education	0.028	2.35 (1.09-5.03)	0.019	2.55 (1.16-5.59)
<b>Ethnicity (Female)</b>				
Muslim	Ref		Ref	
Other ethnic groups	0.014	1.95 (1.14-3.33)	0.016	1.97 (1.13-3.32)
<b>Family income</b>				
<Rs. 35000	Ref		Ref	
Rs. 35000- Rs. 75000	0.49	1.15 (0.77-1.75)	0.89	1.02 (0.69-1.54)
>Rs. 75000	0.59	1.12 (0.75-1.65)	0.88	1.03 (0.68-1.54)



## Discussion

In the present study, the estimated point prevalence of primary subfertility was 6.08% and secondary subfertility was 8.40% in women in the reproductive age group (15-49 years). The prevalence of primary subfertility was comparatively less compared with the results of a large population survey by Boivin, *et al.* [9], which pointed out that primary subfertility prevalence ranged between 6.9% to 9.3% in less developed countries. The prevalence of primary and secondary subfertility rises with increasing levels of education.

The lack of a proper and consensual definition of subfertility is a problem in reporting and comparing the prevalence rate of subfertility [17]. The present study assessed the prevalence rate using the clinical definition of primary and secondary subfertility, which has been used in most studies worldwide [9,13] and in the ICD 10 classification of subfertility. We recruited currently married women to estimate the prevalence rate, as an unmarried woman expecting a child is a rare phenomenon in Asian cultures.

Our study pointed out that secondary subfertility was higher than primary subfertility. Similar results were found in previous studies in Sri Lanka. In Colombo district, a cross-sectional study in 2006 estimated the primary subfertility rate as 5.25% and the secondary subfertility rate as 10.07%, indicating that secondary subfertility is more prevalent than primary subfertility [11]. A similar study done in 1994 revealed that the point prevalence of primary subfertility was 4.05% and secondary subfertility was 16.0% [7]. The secondary subfertility prevalence rate is reported to be high compared to the primary subfertility rate in other South Asian countries. Pakistan reproductive health and family planning survey revealed a subfertility prevalence rate of 21.9% (primary 3.9% and secondary 18%) [18].

It is evident from the literature and the findings from the present study that the primary subfertility rate has increased over the years in Sri Lanka. Increasing the age of first marriage could be one of the reasons for the increased prevalence of primary subfertility [19]. According to the 2016 Demographic and Health Survey Sri Lanka (DHS-SL) report, the age at first marriage for women was 23.7 in Sri Lanka, which is slightly higher than the figure in 2006 DHS -SL, which was 23.2 [20]. The same survey reported that the median age for marriage in the Colombo district was 24.9 years, which indicates that women in the Colombo district get married late compared to the national average. Further, the high prevalence of overweight and obesity among women in urban areas of Colombo, Sri Lanka [21] would be another possible reason for this high prevalence of subfertility in Colombo district. The prevalence of secondary subfertility is decreased in the present study compared to the study done in 2006 (10.07%). One of the most common causes of secondary subfertility is postpartum and post-abortion sepsis [22].

Improvement in postpartum and post-abortion care over the past years would be a reason for this reduction in the prevalence of secondary subfertility.

According to the logistic multivariate regression analysis, female partners with a tertiary level of education had a significantly higher prevalence ( $p < 0.05$ ) rate of primary subfertility than female partners who had no or a primary level of education. The 2016 Demographic and Health Survey report revealed that the median age at first marriage among women with 13 years of education was 26.2 years, which was five and a half years higher than the age at first marriage among women who had no education [20]. The increased age of first marriage for women with higher education may have contributed to this, as there is proven evidence that fertility rates for women decrease with increasing age [14].

The lowest prevalence was reported in study participants belonging to the Moor ethnicity in both primary and secondary subfertility. This low prevalence was significant among female partners in the Moor ethnic group with secondary subfertility. Early marriage would be a reason for the low prevalence of subfertility in this ethnic group.

The present study revealed the employed percentage as 38.8% (1206 out of 3104) among eligible families. According to the 2016 Demographic and Health Survey Report -Sri Lanka [20], the percentage of employed women among ever-married women aged 15-49 was 39.0 % in Colombo district. Therefore, the study population reflects the actual population of the Colombo district.

Population-based study with face-to-face interviews and prospective data collection with a large sample size were the strengths of this study. There are some limitations in this study. Despite, extensive data collection with a structured questionnaire to identify sub-fertile couples, the present study relied on the women's responses, and their responses may be inaccurate in this sensitive issue. The diagnosis of subfertility is on the epidemiological-based questionnaire and not with a specialized investigation is another limitation of this study.

## Conclusions and recommendations

The prevalence of primary subfertility increased progressively over the years in Sri Lanka. Nearly one in seven (15.0%) eligible couple is suffering from primary or secondary subfertility. A significant high prevalence of primary subfertility was reported among women between 25 to 35 years of age, women with a tertiary level of education and employed. The development of effective and rational public health policies for the prevention of subfertility and increased availability of advance reproductive technology facilities should be considered. Further research to find out the prevalence of underlying pathology for subfertility and risk factors would be recommended.

## Competing interests

Authors declare that they have no conflict of interest.

## Ethics approval and consent to participate

Ethics clearance was granted by the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka. Informed written consent was obtained from each participant prior to data collection. (RefNo: P/282/12/2017).

## Funding

None.

## Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## Authors contribution

GG was the principal investigator and was involved in designing the study, development of the study instrument, supervise data collection and conducting statistical analysis. SG and MW were the supervisors and provided the technical guidance and did the overall supervision. GG drafted the manuscript and SG and MW did the proof reading and modified the manuscript.

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