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Women with schizophrenia in Kosovo have worse clinical presentations compared to their male counterparts: a cross-sectional study

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Abstract

Objective: Gender differences have been reported in schizophrenia and suggested that later onset, predominant affective symptoms and better functioning are reported in women, while there is a higher prevalence with more severe negative symptoms and a higher comorbidity for substance abuse in men. However, since the majority of data comes from high-income countries, it is almost unknown whether gender differences exist in people with schizophrenia from socially and economically diverse contexts. The objective of this study is to explore gender differences in socio-demographic and clinical characteristics in a sample of people with schizophrenia in Kosovo, a low- and middle-income country (LMIC).

Materials and methods: The study included 101 patients with schizophrenia recruited from community services. Data on demographics, socio-economic characteristics, use of psychological therapy, and medication was collected through direct interviews. Clinical symptoms were assessed by using a combination of self-rated and researcher-rated measures. Gender differences were examined using chi-square test, independent sample t-tests, and univariate analysis of variance.

Results: The sample was composed of 31.7% (n=32) women. Most demographic characteristics did not differ by gender, apart from marital status (a higher proportion of women were separated; p=0.010). Women presented with more depressive (p=0.010) and paranoid symptoms (p=0.011), and attended psychological therapy less frequently (50% women vs 80% men; p=0.014). For both genders, attending psychological therapy was associated with lower negative symptoms (p=0.002).

Conclusion: Women with schizophrenia had worse clinical presentation compared with men, and reported lower psychological therapy attendance. More research is needed to better describe schizophrenia in LMICs, and to understand whether access to mental health services, particularly psychological therapy, is attributable to clinical or contextual factors. Offering psychological therapy to people with schizophrenia of either gender could alleviate the burden of negative symptoms.

Keywords

Gender Differences, Schizophrenia, Negative Symptoms, Depression, Paranoid Symptoms, Low- To Middle-Income Country

INTRODUCTION

Gender differences have been widely reported in schizophrenia and other psychotic disorders (Jablensky et al., 1992; Ochoa et al., 2012; Riecher-Rössler et al., 2018). The methodological shortcomings of these reports, for example – the inclusion of non-representative samples and exclusion of some diagnostic categories, like a schizoaffective disorder where women are usually overrepresented – do not allow definitive conclusions about the role played by gender in the aetiology (cause) of the disorder. However, some data on gender differences have been consistently reported: men have a slightly higher incidence of schizophrenia, worse negative symptomatology, and a greater likelihood of substance use (i.e., alcohol and cannabis), while women have a later age of onset (with a second peak around the age of 45), more severe affective symptoms, and overall better social functioning, treatment response, and course of illness (Goldstein and Link, 1988; Prat et al., 2018; Riecher-Rössler et al., 2018). However, findings about the role of gender in schizophrenia (and in the epidemiology of schizophrenia in general) are almost entirely derived from research conducted in high-income Western countries. The idea that the epidemiology of schizophrenia is similar worldwide (Jablensky et al., 1992), has been revised in light of the relatively new data on variations of incidence of psychosis based on geographical regions (Morgan et al., 2016; Cantor-Graae and Selten, 2005). Therefore, it is crucial to extend our research to more economically and socially diverse settings (Morgan et al., 2016). This is even more important considering that some contextual factors, such as being an immigrant, gender role stereotypes, social deprivation, stigma, and urbanicity, (Cantor-Graae and Selten, 2005; Cauce et al., 2002; Ferrari et al., 2018; Hjern et al., 2004) can increase the risk of developing schizophrenia. These factors not only have an overall negative impact on mental health (Priebe et al., 2010), but also can shape the way individuals, and society as a whole structure their beliefs around illness and care-seeking (Ferrari et al., 2018).

The role of contextual factors is particularly relevant to low- and middle-income countries (LMICs) wherein social and financial difficulties along with difficulties with the healthcare systems (Asher et al., 2017; Maric et al., 2019) contribute to a large treatment gap in psychosis, with only about 45% of people receiving care for their illness (McDaid et al., 2005; WHO, 2014).

Overall, there is a paucity of data about the role of gender in schizophrenia in LMICs from Southeastern Europe. Namely, one study reported a higher prevalence of delusional symptoms in women and a higher prevalence of anxiety and depressive symptoms in men in Zagreb and Sofia (Hambrecht et al., 1992). A more recent study investigating differences in clinical and functional outcomes of patients with schizophrenia showed that, in Central and Eastern European countries, male patients had a higher likelihood of negative symptoms, alcohol and other substance use, and were younger at the time of first contact with services. The same study reported that a higher proportion of females were in a steady relationship and able to live independently, and that while women showed higher rates of clinical remission at 12, 18, and 36-month follow-ups, no differences were reported in men (Novick et al., 2016). To the best of our knowledge, none of the above studies included Kosovo, and no other research investigating gender differences in schizophrenia has been conducted in other Southeastern European countries.

The current study focuses on a sample of subjects with schizophrenia from Kosovo, a low-income country in Southeastern Europe. Although the country is going through a period of rapid socio-economic changes, its socio-economic status is still deeply affected by the aftermath of war, which is known to profoundly impact mental health (Arenliu et al., 2016; Priebe et al., 2010). Moreover, the presence of culturally imposed gender roles originating from a patriarchal view of life (Färnsveden et al., 2014) can differently affect the way men and women both express mental health problems and seek professional help and treatment. Previous studies indicate that, overall, men and women in Kosovo face similar barriers in accessing healthcare. However, women, especially those from rural areas, appear to have more socio-cultural barriers than men (Goebbels et al., 2017). Kosovo has until the end of the war in 1999 relied only on regional hospitals where psychiatric services were provided in neuropsychiatry wards. Since then the mental health services have developed in delivering services in community mental health centres (seven centres in main cities), which provide home care services and daily activities in centres, especially for chronic psychiatric patients. Kosovo lacks any civil society organisation representing mental health patients or their families (Fanaj and Mustafa, 2018).

Therefore, this study aims to explore whether demographic, socio-economic, clinical and access to pharmacological and psychological therapy differences exist between women and men in a sample of Kosovar patients with schizophrenia. Results from this study could contribute to a deeper understanding of the clinical expression of schizophrenia, and its prognosis and treatment in relation to socio-cultural contexts, healthcare systems and professional resources.

METHODS

The study sample was part of a larger population of patients with psychosis recruited in the IMPULSE project, a multisite study investigating the effectiveness and implementation of a digitally supported psychosocial intervention for psychosis in Southeastern European countries (Jovanovic et al., 2019). Patients were selected based on the following inclusion criteria: aged at least 18 years, in psychiatric treatment for at least three months, a clinical diagnosis of schizophrenia or other non-affective psychotic disorder (ICD-10 F20-F25) (World Health Organization, 1992), and capable of giving informed consent. Patients were excluded if they had either a diagnosis of organic brain disorder or severe cognitive impairment (IQ<70) due to barriers for providing informed consent and responding to the study interview. The study sample was composed of 101 Kosovar participants recruited through two community mental health centres in the cities of Pristina (n=46) and Ferizaj (n=55). The inclusion of these two cities covered both urban and rural parts of the country, so guaranteeing that clinical differences potentially associated with the socialcultural background are represented in this sample.

All participants underwent a comprehensive sociodemographic and clinical assessment as part of the baseline time point of the IMPULSE clinical trial (Jovanovic et al., 2019). Ethics approval was obtained from the institutional ethics committee of the University of Pristina; all participants gave written informed consent before taking part in the study.

Data collection

Data about demographic, clinical, and socio-economic characteristics was collected during individual interviews with participants by trained researchers. Information about self-reported gender identity, age, employment, level of education, marital status, prescribed medication, and psychological therapy attendance (including setting, individual, or group) in the previous six months was obtained with an ad hoc researcher-administered questionnaire. Information on employment status and monthly income were obtained through the Manchester Short Assessment of Quality of Life (MANSA) (Priebe et al., 1999).

The severity of clinical symptoms was evaluated with three clinical measures: the Brief Symptom Inventory (BSI) (Derogatis, 1993), the 24-item version of the Brief Psychiatric Rating Scale (BPRS), (Lukoff et al., 1992) and the Clinical Assessment Interview for Negative Symptoms (CAINS) (Kring et al., 2013). From the BSI, nine symptom dimensions were derived: somatisation, obsessioncompulsion, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. From the BPRS, a total rating and its five subscales (anxiety and depression, negative symptoms, thought disorder, activation, and hostility) were calculated (Giacco et al., 2012). Finally, two subscales, Motivation and Pleasure (MAP) an Expression (EXP), were obtained from the CAINS. For all measures, higher scores indicate a worse severity of clinical symptoms.

Data analysis

Women and men were compared in terms of demographic, socio-economic, and clinical characteristics using χ^2 and an independent sample t-test. As it emerged that a higher proportion of men compared with women attended psychological therapy (see Results section), Multivariate Analysis of Variance (MANOVA) was carried out to explore whether there was an interaction between gender and attending psychological therapy on severity of clinical symptoms; BPRS total score and subscales, BSI subdomains, and MAP and EXP subscales served as outcome variables in three separate MANOVAs.

All data analysis was carried out using Statistical Package for Social Sciences (SPSS) version 23.0.

RESULTS

Whole sample. Of the total study sample, 31.7% (n=32) were women and 68.3% (n=69) were men (Table 1). The mean age of the whole sample was 43.7 years (SD=9.6); 50.5% (n=51) of the participants reported completing

high school, and 42.6% (n=43) reported being single. Almost the entire sample reported being unemployed (92.9%; n=92) and receiving state benefits (95.0%; n=96). All participants had a clinical diagnosis of schizophrenia. The average number of prescribed antipsychotics was 1.5: 50% of the sample (n=47) was on second generation antipsychotics (SGA), 18.1% (n=17) on first generation antipsychotics (FGA), and 32% (n=30) on both FGA and SGA, while 6.9% (n=7) patients were not on any antipsychotics (Table 1). The majority of the participants (72.3%; n=73) reported having accessed psychological therapy treatment (of any kind) in the past six months. The different types of intervention were grouped into four main categories: individual (15.1%; n=11), group (2.7%; n=2), a combination of both individual and group psychological therapy interventions (64.4%; n=47), and other not specified forms of psychological therapy (17.8%; n=13).

Comparison between women and men. There were no statistically significant differences between women and men across age, employment, and level of education. However, a difference in marital status was observed, with a higher proportion of women being separated, and a higher proportion of men being either single or in a stable relationship (p=0.010; Table 2). No difference between women and men was detected in having a monthly income or state benefits. In women, higher depressive (women=1.7±1.1, men=1.1±0.8; p=0.010) and paranoid symptoms (women= 1.6 ± 1.2 , men= 1.1 ± 0.8 ; p=0.011) were reported in the BSI questionnaire (Table 3). Additionally, a trend was observed towards higher interpersonal sensitivity symptoms in women (1.7±1.2) than in men $(1.3\pm1.0; p=0.050)$. The presence of higher depressive symptoms in women was also confirmed by objective (researcher-rated) evaluation through the anxiety and depression BPRS subscale (women=13.9±5.3, men=11.4 \pm 4.7; p=0.016). There were no differences in terms of either number or type of antipsychotic medications. It emerged that a higher proportion of men (79.7%; n=55) compared to women (56.3%; n=18) attended psychological therapy (p=0.014); however, no differences emerged between the two groups in terms of the type of intervention (Table 3). Finally, the MANOVA showed that there was no interaction between gender and participation in psychological therapy on clinical symptoms; however, the main effect of psychological therapy was found on negative symptoms [F(2, 85)=6.34,p=0.003; Wilks' lambda=0.870], specifically on the MAP subscale of the CAINS, indicating that participants who attended a psychological therapy in the last six months had less severe negative symptoms in the domain motivation and pleasure (15.6±6.8) than those who did not attend therapy (20.9±6.3; p=0.002).

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Socio-demographic measures	
Gender [n (%)]	
Women	32 (31.7%)
Men	69 (68.3%)
Age in years [mean (SD)]	43.7 (9.6)
Employment [n (%)]	
Paid employment	3 (3.0%)
Sheltered employment	2 (2.0%)
Unemployed	92 (92.9%)
Other	2 (2.0%)
Level of education [n (%)]	
Elementary or less	44 (43.5%)
High school graduated	51 (50.5%)
University/College graduated	6 (6.0%)
Marital status [n (%)]	
Single	43 [42.6%]
Married/Cohabiting/Civil or any type of partnership	38 (37.6%)
Separated/Divorced/Widowed	20 (19.8%)
Monthly income [n (%)]	
Yes	7 (7.0%)
No	93 (92.1%)
State benefit [n (%)]	
Yes	96 (95.0%)
No	5 (5.0%)
Clinical measures	
BSI [mean (SD)]	
Somatisation	1.1±0.9
Obsessive-compulsive	1.5±0.9
Interpersonal sensitivity	1.4 ± 1.1
Depression	1.3±0.9
Anxiety	1.3±1.0
Hostility	0.7±0.8
Phobic anxiety	1.1±1.0
Paranoid ideation	1.3±1.0
Psychoticism	1.3±0.9
BPRS [mean (SD)]	1.5±0.7
	50.0.12.0
Total score	50.9±13.0
Anxiety depression	12.2±5.0
Negative symptoms	7.8±3.5
Thought disorder	6.9±3.2 5.5±2.3
Activation	
Hostility	5.7±2.6
CAINS [mean (SD)]	17.2.7.0
Motivation and Pleasure	17.2±7.0
Expression	5.1±3.7
Access to psychological therapy [n (%)]	
Yes	73 (72.3%)
No	28 (27.7%)
Type of psychological therapy [n (%)]	11 (15.1%)
Individual	2 (2.7 %)
Group	47 (64.4%)
Both individual and group	13 (17.8%)
Other psychological therapy not specified	
Number of Antipsychotics [mean (SD)]	1.5±0.6
Type of antipsychotic [n (%)]	
FGA	17 (18.1%)
SGA	47 (50.0%)
Both FGA and SGA	30 (32.0%)
No antipsychotic	7 (6.9%)

Table 1: Clinical characteristics of the whole sample (n=101).

BSI= Brief Symptom Inventory; BPRS= Brief Psychiatric Rating Scale; CAINS= Clinical Assessment Interview for Negative Symptoms; FGA= first generation antipsychotics; SGA= second generation antipsychotics

	WOMEN	MEN	STATISTICS
	(n=32)	(n=69)	t/x²(df); p value
Age in years (mean ±SD)	43.2±6.2	43.9±10.8	-0.386 (94.3); p=0.701
Employment [n (%)]			
Paid employment	2 (6.3%)	1 (1.4%)	3.55 (3); p=0.314
Sheltered employment	0 (0.0%)	2 (2.9%)	
Unemployed	30 (93.8%)	64 (92.8%)	
Other	0 (0.0%)	2 (2.9%)	
Level of education [n (%)]			
Elementary or less	13 (40.6%)	31 (44.9%)	1.03 (2); p=0.599
High school graduated	16 (50.0%)	35 (50.7%)	
University/College graduated	3 (9.4%)	3 (4.3%)	
Marital status [n (%)]			
Single	11 (34.4%)	32 (46.4%)	9.27 (2); p=0.010
Married/Cohabiting/Civil or any type of	9 (28.1%)	29 (42.0%)	
partnership			
Separated/Divorced/Widowed	12 (37.5%)	8 (11.6%)	
Monthly income [n (%)]			
Yes	2 (6.3%)	5 (7.2%)	0.03(1); p=0.854
No	30 (93.8%)	64 (92.8%)	
State benefit [n (%)]			
Yes	32 (100%)	64 (92.8%)	2.44(1); p=0.118
No	0 (0.0%)	5 (7.2%)	

Table 2: Comparison between female and male participants with schizophrenia across socio-demographic characteristics

DISCUSSION

This study explored gender differences in a sample of patients with schizophrenia in Kosovo. To the best of our knowledge, this is the first study of its kind and one of the few in Southeastern Europe. Our results showed that women and men were comparable in terms of demographic and socio-economic features except for marital status, where a higher proportion of men reported being single and a higher proportion of women reported being separated or divorced. At a clinical level, both men and women presented with a similar level of psychopathology as measured by the BPRS (average rating of about 50 in the BPRS in both groups) which, overall, could be interpreted as markedly ill (Leucht et al., 2005). However, when specific symptoms were analysed, it emerged that worse anxiety and depressive symptoms were reported in women than in men which corroborates previous findings from both clinical and general populations about

higher affective symptoms in women (Arenliu et al., 2016; Riecher-Rössler et al., 2018; Seedat et al., 2009). Indeed, as subjective anxiety (as measured by the anxiety subscale from BSI) did not result significantly different between women and men we could argue that the difference emerged from the BPRS anxiety-depression subscale would be mainly driven by affective symptoms. Also, and in line with results from a recent study (Riecher-Rössler et al., 2018), paranoid ideation was found to be more severe in women than in men. Conversely, our findings did not confirm previous data about the presence of higher rates of negative symptoms in men in Central and Southeastern European countries (Novick et al., 2016). As reported elsewhere (Riecher-Rössler et al., 2018), the association between gender differences and clinical symptoms could be attributable to other factors like comorbidity and substance use, data that was not systematically collected in the current study. Therefore, definitive conclusions about a more severe clinical presentation in women compared with men cannot be drawn.

	Women	Men	Statistics
			t/x²(df); p value
BSI (mean ±SD)			
Somatisation	1.4±0.9	1.0±0.9	1.73 (98); p= 0.087
Obsessive-Compulsive	1.7±1.0	1.4±0.9	1.88 (97); p= 0.062
Interpersonal sensitivity	1.7±1.2	1.3±1.0	1.98 (98); p= 0.050
Depression	1.7±1.1	1.1±0.8	2.63 (97); p= 0.010
Anxiety	1.4±1.0	1.2±1.0	1.10 (99); p= 0.274
Hostility	0.9±0.9	0.6±0.7	1.75 (99); p= 0.082
Phobic anxiety	1.3±1.2	0.9±1.0	1.74 (98); p= 0.085
Paranoid ideation	1.6±1.2	1.1±0.8	2.59 (97); p= 0.011
Psychoticism	1.5±1.1	1.2±0.8	1.52 (98); p= 0.132
BPRS (mean ±SD)			
Total score	51.8±14.1	50.5±12.6	0.46 (98); p=0.650
Anxiety depression	13.9±5.3	11.4±4.7	2.45 (99); p=0.016
Negative symptoms	7.1±3.3	8.2±3.6	-1.50 (99); p=0.139
Thought disorder	6.5±2.4	7.0±3.5	-0.82 (99); p=0.416
Activation	5.2±2.4	5.7±2.2	-0.96 (99); p=0.340
Hostility	6.2±2.7	5.4±2.5	1.43 (99); p=0.155
CAINS (mean ±SD)			
Motivation and Pleasure	17.8±7.3	16.9±6.9	0.54 (88); p= 0.591
Expression	4.7±3.5	5.3±3.8	-0.82 (99); p= 0.414
Access to psychological therapy [n (%)]			
Yes	18 (56.3%)	55 (79.7%)	6.00 (1); p=0.014
No	14 (50.0%)	14 (50.0%)	
Type of psychological therapy [n (%)]			
Individual			
Group	2 (11.1%)	9 (16.4%)	1.77 (3); p=0.622
Both individual and group	1 (5.6%)	1 (1.8%)	
Other psychological therapy not specified	13 (72.2%)	34 (61.8%)	
	2 (11.1%)	11 (20.0%)	
Number of Antipsychotics (mean ±SD)	1.4±0.6	1.5±0.6	-1.04 (92); p=0.302
Type of antipsychotic [n {%]]			
FGA	6 (18.8%)	11 (15.9%)	2.98 (3); p=0.395
SGA	18 (56.3%)	29 (42.0%)	
Both FGA and SGA	6 (18.8%)	24 (34.8%)	
No antipsychotic	2 (6.3%)	5 (7.2%)	

BSI= Brief Symptom Inventory; BPRS= Brief Psychiatric Rating Scale; CAINS= Clinical Assessment Interview for Negative Symptoms; FGA= first generation antipsychotics; SGA= second generation antipsychotics

When treatment was compared between genders, the two groups did not differ in prescribed antipsychotic medication as previously found for general healthcare services in Kosovo (Dixit et al., 2016). However, the vast majority of men (80%; n=55) reported having accessed psychological therapy in the previous six months, compared with only about 56% (n=18) of women. In the light of the aforementioned worse clinical paranoid and depressive symptoms in women compared with men in our sample, we can speculate that the difference between genders in attending psychological therapy might be associated with potential social factors, like stigma or other socio-cultural determinants. These factors might make women more reluctant to seek help for their mental health, thereby hindering their access to psychological therapy. Alternatively, it might be also possible that, based on literature reporting the overwhelming decision-making power of men over women in the household, (Dixit et al., 2016; Färnsveden et al., 2014) women have less opportunity to express their need for psychological support in the first place. Yet, regardless of gender, attending psychological therapy was reported to have a positive effect on the clinical presentation for either gender, in particular, on negative symptoms. Indeed, in line with results from a recent meta-analysis reporting that negative symptoms in psychosis can modestly benefit from psychological and psychosocial interventions (Lutgens et al., 2017), our findings suggest that participants who received some sort of psychological intervention in the previous six months had less severe negative symptoms compared to those who did not receive a psychological intervention. Differences were found in motivation and pleasure for relationships and social/recreational activities, which are well known challenging negative symptoms to treat. This result holds important clinical and research implications: on one hand, it highlights the importance of offering this type of support to improve symptoms and quality of life, which in turn could have indirect positive consequences on the level of functioning and overall burden of the illness both at an individual and societal level. On the other hand, more research is needed to understand what type of psychological treatment, what duration, and what frequency represents the best balance for patients' benefit while taking into consideration contextual factors, such as sustainability of the treatment in terms of cost and professional/clinical capacity. The latter factor is a crucial point in Kosovo and other LMICs in Southeastern Europe given the financial and institutional barriers that people face due to the aftermath of war and related healthcare service transformations.

This study has several strengths. To the best of our knowledge, this is the first study investigating gender differences in a sample of people with schizophrenia in LMICs in Southeastern Europe. All participants underwent a comprehensive clinical assessment covering the full range of relevant psychopathology for the disorder, including both participant-rated and researcherrated measures which reconcile subjective and objective evaluations of clinical symptoms. Yet, the study presents several limitations: data on socio-economic status were self-reported and it was not possible to check their reliability; similarly, some clinical measures, like the BSI, were participant-rated, which limits the interpretability and generalisation of our results. Additionally, although participants were asked details about psychological therapy (i.e., frequency, duration, and type of approach), it was not possible to collect this information across the whole sample or to systematically check the accuracy of the information with the treating clinician and/or medical records. Likewise, comparison between genders on other variables, such as substance abuse, level of functioning and response to treatment, could not be investigated as those variables were not collected in the original study from which this sample was derived.

As reported above, the lack of collateral information about comorbidity and/or the risk factors associated with the illness (i.e., substance use), and duration of illness did not allow for a more comprehensive and definitive interpretation of findings about the clear association of gender with clinical symptoms. Finally, the limited sample size does not permit generalising the findings to other LMICs in Southeastern Europe.

CONCLUSION

This study corroborated previous data about the presence of gender differences in schizophrenia and showed, for the first time in a LMIC in Southeastern Europe, that men and women present with different socio-demographic and clinical characteristics. This has some important clinical implications as it suggests that women and men with psychosis experience the disorder differently and, therefore, could benefit from individualised care based on their predominant clinical symptomatology. Moreover, as our results suggested that psychological therapy, regardless of gender, is associated with lower levels of negative symptoms, higher attendance should be promoted, especially among women who often experience additional contextual barriers to treatment. It would be advisable to take gender into account when providing care so that each individual can receive the best treatment based on their needs for the best prognostic outcome. From a research perspective, gender could be used to stratify samples so that a better understanding can be gained about its role in psychosis. Ultimately, rigorous research is needed to better characterise the clinical presentation of people with

psychosis in LMICs and to understand whether access to mental health services, particularly psychological therapy, is attributable to clinical characteristics or contextual factors, both social and economic.

DECLARATIONS

Authors' contributions: MR, NJ and AA contributed to the study conception. MR contributed to data preparation, analysis, interpretation of results and first drafting of the manuscript and final version. AA, NJ critically revised for important intellectual content. FU, JK and DB contributed to data preparation and critically revised for important intellectual content. All authors read and approved the final version of the manuscript.

Ethics approval: all procedures described in this study are in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. All procedures were approved by the local ethics committee from the Hospital and University Clinical Service of Kosovo – Ethics Committee 2019-85.

Conflicts of interest/Competing interests: the authors have no financial or non-financial interests to declare.

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Informed consent: all participants gave written consent prior to participation in the study.

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