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Original Scientific Paper

OUTCOME IN ELDERLY PATIENTS WITH ANCA – ASSOCIATED GLOMERULONEPHRITIS MANAGED WITH IMMUNOSUPPRESSIVE TREATMENT

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SUMMARY – The most common cause of rapidly progressive glomerulonephritis in elderly, anti-neutrophil cytoplasmic antibody-associated glomerulonephritis (ANCA-GN), demands immunosuppressive therapy (IS) regimen in a multi-morbid disease burdened population. Our aim was to assess outcome differences in two age groups.

The study included a total of 38 ANCA-GN renal limited patients (18 men) treated from 1990 to 2018, of which 11 were 65 years of age and older (median 70, min. - max. 66 - 79 years), and 27 younger than 65 (median 55, min. - max. 23 - 64 years). All patients were treated with mono/combination of IS.

Most commonly applied IS in elderly was combination of IV cyclophosphamide and corticosteroids (CS) (in 9 [81.8%]), while in younger it was a combination of CS and cyclophosphamide or rituximab (59.2%). Older patients had comparable mortality (3, [14.8%] vs. 4, [27.3%]; P = 0.369), malignancies (1, [3.7%] vs. 1, [9.1%]; P = 0.5) and infectious complications (10, [46.7%] vs. 7, [63.6%]; P = 0.388). Ten patients at the end of the follow up were at renal replacement therapy (RRT), with no difference between age groups (6, [22.2%] vs. 4, [36.4%]; P = 0.369). Interestingly, from initial need for RRT, half of the younger and older patients recovered with IS.

Our findings give more credit to the current paradigm to treat elderly ANCA-GN patients with IS therapy due to the similar outcome of elderly as younger ones.

Key words: *Antineutrophil Cytoplasmic antibodies, Glomerulonephritis, elderly, Immunosuppression, Mortality, Kidney failure*

Introduction

Anti-neutrophil cytoplasmic antibody-associated glomerulonephritis (ANCA - GN) is a clinical entity in which ANCA-associated vasculitis (AAV) is limited to the kidneys, most commonly resulting in rapid progressive kidney failure[1]. Due to the rapidly progressive nature of the disease, fast diagnosis and treatment are crucial[2]. However, treatment with immunosuppressive agents also carries significant risks, especially in the elderly population of patients[3]. The incidence of ANCA-associated rapid progressive glomerulonephritis (RPGN) is known to increase with age, therefore being the most common cause of RPGN in the elderly[4,5]. Furthermore, current data suggest that younger patients frequently develop end-stage renal disease (ESRD) during follow-up[4,6]. On the other hand, older patients have increased mortality, possibly associated with the disease itself or possibly to the ad-

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ministered treatment[4,6,7]. The fact that morbidity and mortality were the highest in the first year after diagnosis in the majority of reported cases raises the question of whether this was due to the disease process itself or it was a consequence of immunosuppressive treatment administration in a comorbid burdened cohort of patients[4-6].

As the world's population is ageing, it would be helpful if recommendations regarding elderly and very elderly patients with ANCA-GN were addressed.

The aim of this study was to evaluate renal outcomes in the elderly population with ANCA-GN treated with immunosuppressive therapy in comparison with a younger cohort.

Subjects and Methods

All adult patients (older than 18 years) diagnosed with limited renal ANCA-GN from 1990 to 2018 at the Department of Nephrology, Arterial Hypertension, Dialysis and Transplantation of University Hospital Centre Zagreb were enrolled. Retrospective data and follow-up were derived from medical records and the hospital information system. All patients were enrolled in our study if pathohistological analysis revealed pauci-immune glomerulonephritis along with the exclusion of secondary causes and systemic involvement. Patients were divided into two groups, younger than 65, and 65 or older, according to the World Health Organisation definition of older patients.

The data were collected at presentation, during the first two years of diagnosis, and at the last control. Patients' anthropometric measures, blood pressure, preexisting comorbid disease, signs of infection, and the applied therapy were derived from medical records. Furthermore, data regarding kidney function and disease activity were used, namely serum creatinine (SCr), proteinuria, red cells in urine sediment (RCU), and ANCA titre. Renal function was assessed using CKD-EPI equation[8] to estimate glomerular filtration (eGFR), as well as staged according to KDIGO staging[9]. Arterial hypertension was considered as blood pressure > 140/90 mmHg or using antihypertensive medication.

SCr was measured by the modified Jaffe assay and used to calculate eGFR[10]. Urinary protein concentrations were determined using latex-enhanced immunonephelometry on a Behring Nephelometer II (Dade Behring, Marburg, Germany).

The pathohistological analysis of biopsy tissue was done by light microscopy using hematoxylin and eosin, methenamine silver, and periodic acid-Schiff stainings. Also, immunofluorescence with IgG, IgA, IgM and complement staining, as well as electron microscopy was done.

Complete remission was defined as recovery of renal function, proteinuria < 0.25 g/dU, and negative urine sediment. Partial remission was defined as proteinuria range 0.25 - 3.5 g/dU, negative urine sediment, and 50% reduction of the initial creatinine value[11].

Therapy was defined as induction therapy, which was separated into intravenous (IV) forms of corticosteroids (CS) as monotherapy or in combination with either cyclophosphamide or rituximab. Maintenance therapy was either monotherapy with azathioprine (AZA) or a combination of CS with AZA or mycophenolate mophetil (MMF).

Each patient's end-point was defined as death by any cause (split into malignancy, infection, cardiovascular-related, or other), hemodialysis dependency or ESRD, or patient loss in follow-up.

Data are expressed as median values with interquartile range (IQR, 25 and 75 percentiles) for continuous variables and with numbers and percentages for categorical variables. Patients were divided into two groups according to age at the presentation (younger than 65 years, or 65 years and older). Differences in medians between groups were assessed by the Mann - Whitney U test. A Fisher exact test was used for group comparisons regarding prevalence. Correlations between parameters were examined using the Spearman's Rho test. The multivariate logistic regression analysis was performed to assess risk factors for ESRD in ANCA-GN for the whole group. The Kaplan - Meier analysis was used to assess ESRD - free renal survival between older and younger cohort. All results were considered statistically significant if $P < 0.05$. Statistical analysis was performed using SPSS, vers.23 (SPSS. Chicago, Inc).

Results

Patients were divided into two groups, those younger than 65 years (group 1) and 65 years and older (group 2). Elderly patients with ANCA-GN had higher sys-

Table 1: Significant clinical parameters at the time of presentation

	< 65 years old	≥ 65 years old	*P*
	n = 27	n = 11	
Age, years	55 (23 - 64)	70 (66 - 79)	<0.001
Female	12 (44.4%)	8 (72.7%)	0.16
Systolic blood pressure, mmHg	140 (120 - 148)	150 (142 - 161)	0.028
Diastolic blood pressure, mmHg	85 (80 - 93)	90 (85 - 90)	0.625
Serum Creatinine, µmol/l	325 (243 - 637)	400 (349 - 665)	0.132
Proteinuria, g/dU	1.55 (0.9 - 2.3)	1.23 (0.63 - 2.53)	0.497
eGFR (CKD-EPI), ml/min/1.73 m2	15 (8 - 26)	11 (6 - 15)	0.023
Active urine sediment	26 (96.3%)	8 (80%)	0.172
Nephrotic syndrome	5 (18.5%)	1 (10%)	0.146
pANCA	20 (74.1%)	10 (90.9%)	0.395

Age is expressed as median (min-max); all other measurements are expressed as either median (interquartile range) or number (%)

Table 2. Clinical parameters at the end of follow-up period

	< 65 years old	≥ 65 years old	*P*
	n = 25	n = 7	
Systolic blood pressure, mmHg	140 (120 - 150)	130 (126 - 138)	0.428
Diastolic blood pressure, mmHg	90 (81 - 90)	80 (76 - 87.5)	0.051
Serum Creatinine, µmol/l	150 (114 - 209.5)	191 (130 - 393)	0.175
Proteinuria, g/dU	0.53 (0.26 - 0.55)	0.55 (0.32 - 1.42)	0.765
eGFR (CKD-EPI), ml/min/1.73 m2	44 (25.5 - 54)	25 (10 - 37)	0.068
Time to infectious complications, months	4 (2 - 8.3)	3 (1 - 6)	0.601
Nephrotic syndrome	2 (8,3%)	0 (0%)	0.43
pANCA	7 (41,9%)	4 (57,1%)	0.659

tolic BP and lower eGFR than the younger cohort. Also, elderly patients had a higher body mass index (BMI) than those younger than 65-year-old ANCA-GN patients. There was no difference in renal function parameters such as sCr and proteinuria between groups at presentation (Table 1). All patients had ANCA positive serology, almost all patients older than 65 years had pANCA positive serology (10, 90.9%) without difference between the groups. Nine patients (24.3%) presented with kidney failure requiring renal replacement therapy (RRT), with no difference between cohorts (3, 27.3%, *vs.*6, 23.1%); *P* = 0.786).

No differences in percentage of crescentic formations were found between the groups (45%, 31.5 - 76, *vs.*48, 23 - 77.5; *P* = 0.734). When separating the forms of crescents, the majority of patients had active crescent lesions, without significant difference between groups (8, 72.8% *vs.* 13, 68.4%; *P* = 0.334).

Table 3. Renal disease outcome at the end of the follow-up period

	< 65 years old	≥ 65 years old	Total
	n = 26	n = 11	
Total remission	6 (23.1%)	1 (9.1%)	7 (18.9%)
Partial remission	11 (42.3%)	6 (54.3%)	17 (45.9%)
No remission (active disease)	9 (34.6%)	4 (36.4%)	13 (35.1%)
of which ESRD	6 (23.1%)	4 (36.4%)	10 (27.0%)

We found that 74.3% of all patients had 1 or more comorbid diseases at the time of presentation, pre-

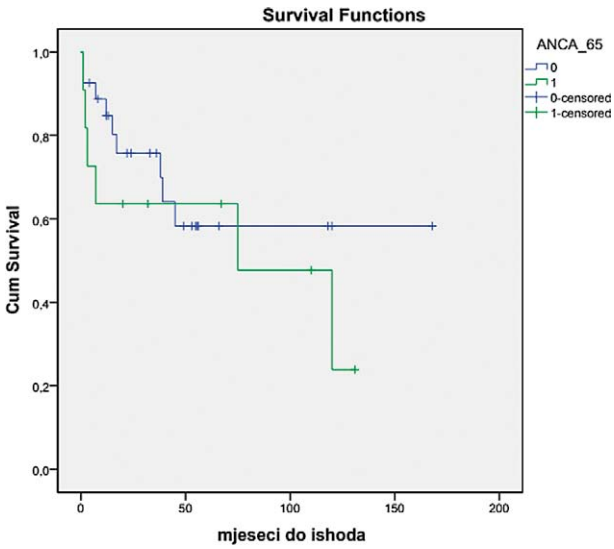

Figure 1. End-stage renal disease (ESRD) - free survival in older (7, 63.4%) and younger (21, 77.8%) groups

dominantly the elderly (10, 90.9%). Arterial hypertension was the most frequent comorbid disease.

There was no significant difference in induction treatment regimen between the groups. The elderly cohort was most frequently treated with a combination of cyclophosphamide and CS (9, 81.8%), while the younger group was predominantly treated with a combination of CS and either cyclophosphamide or rituximab (16, 59.2%). CS monotherapy as a regimen choice was used more frequently in the younger population (11, 40.7% *vs.* 2, 18.2%). That was the group of patients treated at the beginning of the 1990s. Plasmapheresis was done in 6 (16.2%) patients overall, with no difference between younger than 65 and the elderly (4, 15.4% *vs.* 2, 18.2%; $P = 0.833$).

The groups had similar follow-up duration (38.5 months, IQR 15.5 - 55.75, *vs.* 32 months, IQR 3 - 110; $P = 0.820$). After 2 years of follow-up, 11 (84.6%) younger and 4 (66.7%) older patients were still on IS. Combination of oral CS and AZA was the most commonly found maintenance therapy in the younger group (6, 46.2%), while in the older group, the most commonly found therapy was oral CS monotherapy (in 3, 50%). At the end of follow-up, 48.1% of total patients had no IS.

At the end of follow-up there was no difference between younger and older group in renal function parameters like eGFR (44 mL/min/m^2, IQR 25.5 - 54, *vs.* 25 mL/min/m^2, IQR 10 - 37), daily proteinuria (0.53 g, IQR 0.26 - 0.55 *vs.* 0.56 g, IQR 0.32 - 1.42), or systolic blood pressure (140 mmHg, IQR 120 - 150, *vs.* 130 mmHg, IQR 126 - 138; $P > 0.05$) (Table 2).

Both groups had significant beneficial effects on kidney outcome parameters during the follow-up period. According to KDIGO guidelines, 24 (64.9%) of all patients had favourable renal outcomes, with no difference between the groups (17, 65.4%, *vs.* 7, 63.6%; $P = 0.919$). Patients with favourable renal outcomes are comprised of 6 (23.1%) *vs.* 1 (9.1%) total remissions, 11 (42.3%) *vs.*6 (54.5%) partial remissions (Table 3). Unfavourable renal outcomes comprised of ESRD cases, as well as 3 cases of active and still not terminal renal disease in the younger group. Ten patients (26.3%) at the end of follow-up had ESRD and required renal replacement therapy (RRT) with no difference between the younger and older group (in 6, 22.2 %, *vs.*4, 36.4 %; $P = 0.369$). We found no difference in time to RRT between the groups (9 months, IQR 1 - 38, *vs.*2.5 months, IQR 1.2 - 90.7; $P = 0.05$). More importantly, half of the patients who initially presented with ESRD or a need for RRT recovered their renal function upon IS, similarly in older as in the younger group (5, 45.4% *vs.*8, 57.1%). ESRD-free survival was similar between groups (Figure 1.) In multiple logistic regression analysis, higher BMI at presentation was a protective factor for the development of ESRD (OR 0.629, 95% CI 0.411 - 0.962, $P = 0.032$).

Infective complications were recorded in 7 (63.6%) patients in the older cohort and 10 (47.6%) patients in the younger group. The difference in the frequency of infectious complications was not significant between the two groups ($P = 0.388$). The most common infections were urinary tract infections (UTI), with 2 (9.1%) cases in the younger and 3 (30%) in the older population. Also, patients in the older group were more prone to gram-positive sepsis (in 3 of them, 30%). There was no significant difference in time in developing the infectious complications between groups ($P = 0.601$).

There was no difference in occurence of malignant diseases among groups (in 1 younger, 3.7 %, *vs.*1 older, 9.1 %; $P = 0.5$). Seven patients died during follow-up, with no significant difference between two groups (3, 14,8% *vs.*4, 27,3%; $P = 0.369$).

Discussion

The most common cause of RPGN in the elderly is ANCA - GN. In fact, this entity is so common in the elderly that in patients with positive serology, histological confirmation might not even be necessary[12,13]. Our results further confirm these findings, with all patients in our cohort being ANCA positive and 78.9% pANCA positive. However, even if a diagnosis could probably be made without histological confirmation, the delay in ANCA serology testing results in everyday practice would result in an impediment of diagnosis and worse outcome. Therefore, kidney biopsy remains a vital diagnostic procedure, and all patients in our study had histological confirmation of the diagnosis.

There are conflicting results in the literature regarding the treatment of elderly patients with AAV, with a number of studies reporting an increased risk of infection, leucopenia, and even increased mortality[14,15]. The increase in mortality was primarily attributed to death from infections occurring during immunosuppression[15]. However, comparable rates of renal outcome, as well as the similar risk of infection in comparison with younger ANCA-GN patients, were also reported[4,6,16].

In our retrospective study, due to the high index of active crescent formations on kidney biopsy and rapidly progressive pauci-immune glomerulonephritis, all patients were treated with IS, which gave us the opportunity to compare older to younger group of patients with ANCA-GN. We found no significant difference regarding the renal outcome as well as no significant difference in the risk of infection between the two groups. As the elderly group was treated with combination therapy, not having a difference in the frequency of infection is an important fact. Furthermore, we observed no significant difference in mortality between the two groups. Likewise, in our study, the deaths were not preceded by the development of ESRD in both groups, which was contrary to the literature statement that older patients were more likely to die before progressing to ESRD[4-6].

Interestingly, higher BMI at presentation was an independent protective factor against the development of ESRD. It may be that this phenomenon has something to do with reverse epidemiology in ESRD, where higher BMI is better for patients' outcome than malnutrition. Although kidney function at presentation was reported as an independent factor of renal and overall survival[4,6,11,17-21], we did observe such a trend, but without reaching statistical significance.

Importantly, over 50% of patients on RRT at presentation recovered kidney function after the treatment. Similar results were reported by Manno et al., who found that 40% of patients with pauci-immune glomerulonephritis that required haemodialysis at the presentation after IS recovered their renal function regardless of age[22]. The fact that renal function can improve with treatment in a significant proportion of patients, even if the patients presented with the need for RRT, gives a strong argument for administering IS even in elderly patients. Although it is plausible that this population of patients harbours an increased risk of infections, the benefit of avoiding RRT therapy and its complications should certainly be taken into account in clinical decision making[1]. Ultimately, the decision to administer treatment of RPGN in the elderly should not be based on age alone since it is obvious that a subpopulation of elderly patients has a clear benefit from IS. Further studies are needed to recognize this specific patient subpopulation, thus avoiding treating patients with a low probability of treatment success. Furthermore, more studies are needed to investigate the magnitude of the risk of infection in this population of patients more accurately.

The main limitations of this study are the retrospective design and sample size, diversity in therapeutic approaches, and histological results over decades. As AAV and especially ANCA-GN is a relatively rare disease, multicentric prospective research and collaboration would be most welcome and would bring more power to results and conclusions drawn from them, particularly when dealing with a specific subgroup of patients, like the elderly and the very elderly.

In conclusion, when facing the challenge of treating older patients with kidney damage due to ANCA-GN, age alone should not guide our decision because renal recovery after IS can be expected, even in initially severe renal failure.

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Sažetak

ISHOD STARIJIH BOLESNIKA S ANCA GLOMERULONEFRITISOM LIJEČENIH IMUNOSUPRESIVNOM TERAPIJOM

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Najčešći uzrok brzoprogresivnog glomerulonefritisa u starijih je glomerulonefritis s antineutrofilnim citoplazmatskim protutijelima (ANCA-GN, od eng. *antineutrophil cytoplasmic antibody related glomerulonephritis*), a s obzirom na komorbiditete predstavlja izazov u odluci oko primjene imunosupresivne terapije (IS). Cilj ovog istraživanja je usporediti razlike u ishodu dvije dobne skupine bolesnika.

Istraživanje je obuhvatilo slučajeve ANCA-GN ograničenih na bubrege, liječene od 1990. do 2018. godine, njih 38 (18 muških), od kojih 11 ima 65 ili više godina (medijan 70, min.-max. 66 - 79 godina) a 27 mlađih (medijan 55, min. - max. 23 - 64 godina). Svi bolesnici su liječeni monoterapijom ili kombinacijom IS-a.

Najčešće primjenjena IS u starijoj populaciji bila je kombinacija intravenskog ciklofosfamida i kortikosteroida (KS) (u 9 (81,8%)), u mlađoj kombinacija KS s ciklofosfamidom ili rituksimabom (59,2%). Stariji pacijenti imali su sličnu učestalost smrtnosti (3, 14,8% *vs* 4, 27,3%; *P* = 0.369), zloćudnih bolesti (1, 3,7% *vs* 1, 9,1%; *P* = 0.5) i infektivnih komplikacija (10, 46,7% *vs* 7, 63,6%); *P* = 0.388). Deset bolesnika je na kraju praćenja bila ovisno o nadomještanju bubrežne funkcije (NBF) bez razlike u dobnoj skupini (6, 22,2% *vs* 4, 36,4%; P = 0.369). Međutim, od inicijalne potrebe NBF-om se uz IS oporavila polovica starijih i mlađih bolesnika.

Naši rezultati su u skladu trenutačnim stajalištima koja podupiru primjenu IS terapije kod starijih bolesnika sa ANCA-GN zbog usporedivih ishoda i rizika komplikacija kao u mlađih bolesnika.

Ključne riječi: *Antineutrofilna citoplazmatska antitijela, glomerulonefritis, stariji, imunosupresija, mortalitet, kronično bubrežno zatajenje*