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CLINICAL STUDY

Quality of life and psychological well- being in patients with various pacing modes

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Abstract: *Aim:* of the study was to assess the influence of different pacing modes on the quality of life (QOL), anxiety and depression.
Methods: QOL was assessed in 101 patients (58 men, mean age 69.39±14.64 years) with implanted pacemaker (35 patients received VVI pacemaker, 17 patients VVIR, 21 patients DDD, 28 patients DDDR). QOL was measured by the SF-36 and Aquarel questionnaires, anxiety by Beck scale and depression by Zung scale.
Results: No differences in QOL were observed between patients with single chamber and dual chamber pacing. Patients with rate- adaptive pacing had higher scores in SF 36 scales (physical component summary, mental component summary, vitality and bodily pain), Aquarel (chest pain and dyspnea) and they exhibited lower degree of anxiety and depression compared to non-rate-adaptive pacing. Differences were shown only in a group of dual chamber pacemakers, not in the group of single chamber pacemakers. There was a strong correlation between the degree of anxiety and depression and the QOL in pacemaker patients.
Conclusion: Dual chamber rate-adaptive pacing offered better QOL and psychological profile compared to dual chamber non-rate-adaptive pacing. No differences were observed between single chamber and dual chamber pacing *(Tab. 3, Fig. 3, Ref. 24).* Full Text (Free, PDF) *www.bmj.sk.*
Key words: cardiac pacing, rate-adaptive pacing, quality of life, anxiety, depression.

Since the introduction of cardiac pacing using fixed rate ventricular pacemakers (VVI), several sophisticated pacing modes are available.

Physiologic pacing maintaining AV synchrony (AAI, VDD, DDD modes) was shown to improve cardiac hemodynamics. AV synchronous pacing increases stroke volume and cardiac index, as well as decreases atrial pressures by as much as 30–50 %.

AV synchronization has an important role in maintaining an appropriate cardiac output at rest and at lower levels of activity. A number of studies demonstrated that at higher levels of exercise the chronotropic competence is the most important contributor to cardiac output. Both rate adaptiveness and maintained AV synchrony are goals of physiologic pacing. Multiple studies documented hemodynamic benefits of AV synchronous (DDD/R and AAI/R) and rate adaptive pacemakers (VVIR), pacemakers compared to fixed rate ventricular pacemakers (VVI). The hemodynamic benefits of DDDR over VVIR are less clearly documented.

However, it is not clear if hemodynamic improvement achieved by physiological pacing correlates with improved survival, improved symptoms and better health related quality of life (QOL).

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QOL is being increasingly considered as an expected outcome of therapeutic interventions and rehabilitation programs in clinical cardiology. Assessment of the QOL in paced patients may be a better measure of symptomatic improvement than maximal exercise capacity as most paced patients remain at low or moderate levels of physical activity. In the era of rising costs for implantation of highly sophisticated pacemakers is the assessment of QOL (which is an objective measure of the pacing benefit) of substantial value. Unfortunately, most studies concerning QOL in cardiac pacing were performed in a small number of patients or using non-validated questionnaires. Because of different symptomatology QOL questionnaires developed for other cardiac diseases are not appropriate for paced patients. It was proposed to use a combination of a generic and disease specific questionnaires. The SF-36 is a widely used questionnaire, known for its validity and psychometric properties. It was used in cardiology for evaluation of angina pectoris, syncopal patients, heart failure, cardiac surgery patients and other diseases. The SF-36 consists of 36 items that can be combined into 8 health domains and 4 summary scores assessing physical and mental health. Each score is obtained by summation of item scores and is scaled form 0 to 100. Higher score in SF 36 means better QOL of the patient.

A disease specific module added to SF-36 should cover a broad range of symptoms reported by pacemaker patients, should be multidimensional and well validated. The Aquarel questionnaire (Assessment of QUality of life and RELated events) consists of three subscales: Arryhthmia (5 items), dyspnea and

Tab. 1. Demographic characteristics in patients with single-chamber and dual-chamber pacemakers.

	Single-chamber pacemakers (VVI/R) (n=52)	Dual-chamber s pacemakers (DDD/R) (n= 49)	Statistical significance (p)
Men	30	28	0.95
Women	22	21	
Mean age	64.03 ± 13.8	62.7 ± 15.6	0,51
NYHA class I or II	46	41	0.68
NYHA class III or IV	4	5	0.73
History of CAD	50	46	0.67
Hypertension	31	27	0.64
History of diabetes mellitus	11	14	0.38
Mean time from first implantation	6.66 ± 6,64	5.72 ± 4,8	0.32
Mean number of pacemakers implanted	1.38	1.37	0,96
Rate – adaptive pacemaker	17	21	0.39
Sinus node disease	20	11	0.12
AV nodal disease	32	38	

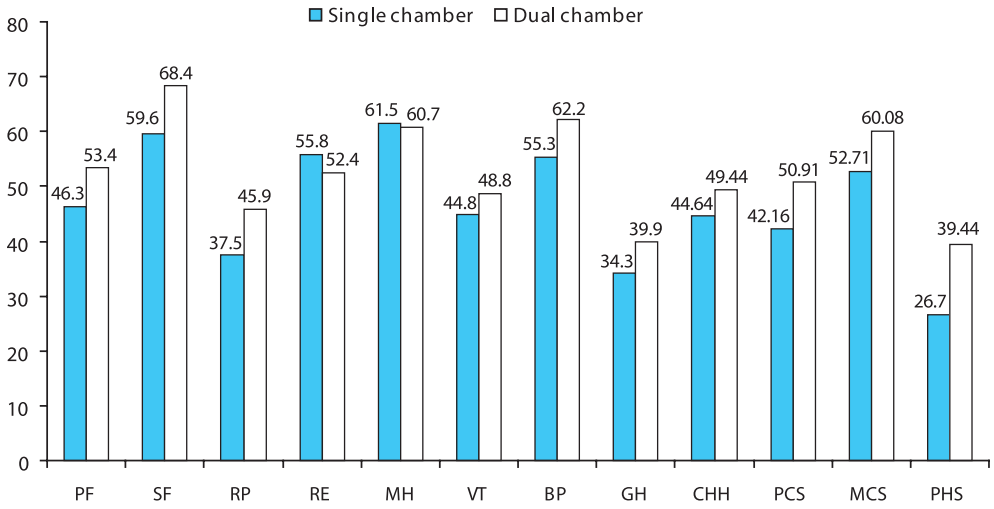

Fig. 1. QOL measured by general scale (SF 36) in patients with single chamber and dual chamber pacemakers. PF – Physical Functioning, SF – Social Functioning, RP – Role limitation due to Physical problems, RE – Role limitation due to Emotional problems, MH – Mental Health, VT – Vitality, BP – Bodily Pain, GH – General Health, CHH – Change in Health, PCS – Physical Component Summary, MCS – Mental Component Summary, PHS – Perceived Health Status, *p<0.05.

exertion (7 items), and chest discomfort (8 items). Lower score in Aquarel questionnaire reflects better outcome with respect to QOL.

The psychometric properties were validated and were shown to be satisfactory. Aquarel questionnaire was used in RASTAF II and OASES pacemaker trial to evaluate various pacing modes in patents with atrial fibrillation.

Aim of the present study was to assess quality of life (QOL), anxiety and depression in patients with different pacing modes.

Methods

QOL was assessed in 101 consecutive patients (58 men, 43 women, mean age 69.39±14.64 years) with implanted pacemaker (PM) during their regular follow-up visit. Mean time from implantation was 6.20±5.81 years. Thirty-five patients received VVI pacemaker, 17 patients VVIR pacemaker, 28 patients DDD pacemaker, 19 patients DDDR pacemaker. Pacemaker was implanted for sick sinus syndrome in 31 patients and atrioventricular block

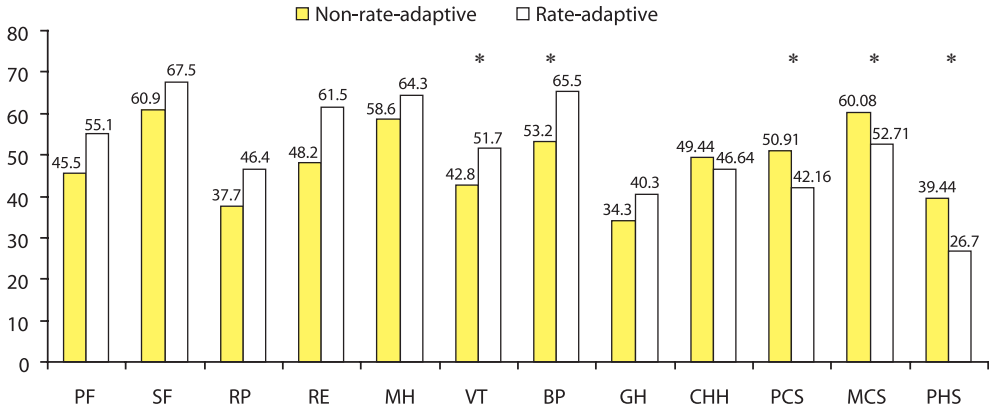

Fig. 2. QOL measured by general scale (SF 36) in patients with rate-adaptive and non-rate-adaptive pacemakers. PF — Physical Functioning, SF – Social Functioning, RP – Role limitation due to Physical problems, RE – Role limitation due to Emotional problems, MH – Mental Health, VT – Vitality, BP – Bodily Pain, GH – General Health, CHH – Change in Health, PCS – Physical Component Summary, MCS – Mental Component Summary, PHS – Perceived Health Status, * p<0.05.

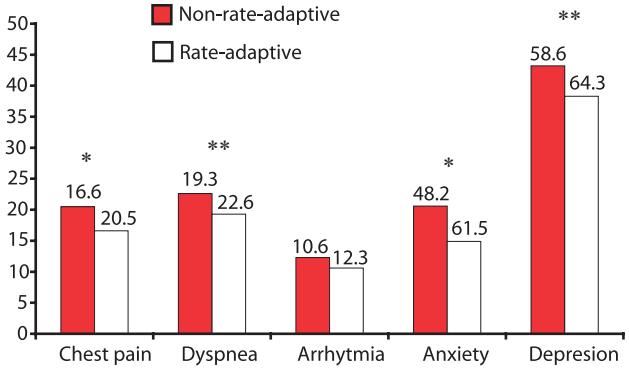

Fig. 3. Anxiety, depression and QOL measured by specific scale (Aquarel) in patients with rate-adaptive and non-rate-adaptive pacemakers. *p<0.05, **p<0.01.

in 70 patients. Demographic and clinical data are shown in the Table 1. There were no significant clinical and demographic differences between patients in single chamber and dual-chamber pacemakers.

QOL was measured by the general health related QOL questionnaire SF-36 in 8 summary scores: physical functioning (PF), social functioning (SF), role limitation due to physical health (RP), role limitation due to emotional problems vitality (RE), bodily pain (BP), mental health (MH), general health perception (GH). In addition, four composite scores were evaluated: 1) change in health over past year (CHH), 2) physical component summary (PCS), 3) mental component summary (MCS) and 4) perceived health status (PHS).

Aquarel was used as a pacemaker patients specific questionnaire. QOL was assessed in three scales – arrhythmia (5 items), dyspnea and exertion (7 items) and chest discomfort (8 items)

Psychological aspects were evaluated by Beck scale for anxiety and Zung depression scale.

Questionnaires were administered in the form of interview and by face to face contact by a trained psychologist during a regular follow-up visits. The psychologist was blinded with respect to type of pacemaker during the interview.

Statistical analysis. Statistical significance in demographic characteristics was tested by chi-square test. Differences in QOL scores were evaluated by Students t test and ANOVA. Correlations were done by the Pearson a Spearman method. P value less than 0.05 was considered significant.

Results

No differences in QOL measured by SF 36 and Aquarel were observed between patients with single chamber and dual chamber PM (Fig. 1). Similarly there were no differences in anxiety (Beck) and depression (Zung) scores.

Significant differences were noted between patients with rate-adaptive and non-rate-adaptive pacing. Patients with rate-adaptive pacing had higher scores in SF 36 subscales reflecting vitality (VT 51.67±20.34 vs 42.76±19.68, p=0.02) and pain (BP 65.49±30.13 vs 53.18±25.99, p=0.03), physical component summary (PCS 50.91±19.9 vs 42.16±19.75, p=0.02), mental component summary (MCS 60.08±17.66 vs 52.71±17.19, p=0.03), and perceived health status (PHS 39.44±20.98 vs 26.7±23.42, p=0.005) (Fig. 2).

Patients with rate-adaptive pacing scored better in Aquarel 1 scale – chest pain (16.58±8.02 vs 20.57±8.28, p=0.016) and Aquarel 2-dyspnea (19.27±6.22 vs 22.63±6.22, p=0.008). Similarly they exhibited lower degree of anxiety (Beck 14.91±11.04 vs 20.82±13.37, p=0.019) and depression (Zung 38.27±8.21 vs 43.16±8.91, p=0.003) (Fig. 3).

By subgroup analysis differences between rate adaptive a non-rate-adaptive pacing appeared only in dual chamber pacemakers, differences were not observed in the group of single

Tab. 2. QOL in patients with single chamber rate-adaptive and single chamber non-rate-adaptive pacemakers.

	Rate-adaptive pacemakers (VVIR) (n= 17)	Non-rate-adaptive pacemakers (VVI) (n= 35)	Statistical significance (p)
SF 36			
Physical Functioning (PF)	49.11 ± 29.43	45.00 ± 26.70	0.616
Social Functioning (SF)	60..29 ± 34.86	59.29 ± 28.50	0.912
Role-Physical (RP)	47.81 ± 44.68	32.44 ± 37.63	0.200
Role-Emotional (RE)	64.71 ± 46.36	51.43 ± 42.27	0.308
Mental Health (MH)	60.24 ± 19.52	62.07 ± 14.92	0.704
Vitality (VT)	45.88 ± 22.37	44.29 ± 21.36	0.804
Bodily Pain (BP)	61.76 ± 32.40	52.17 ± 25.94	0.255
General Health (GH)	32.76 ± 18.57	34.97 ± 16.30	0.664
SF – 36 composite scores			
Change in Health (CHH)	45.59 ± 30.92	43.57 ± 27.35	0.812
Physical Component Summary (PCS)	45.59 ± 30.92	41.68 ± 18.85	0.553
Mental Component Summary (MCS)	55.36 ± 19.96	54.75 ± 16.81	0.908
Perceived Health Status (PHS)	37.35 ± 22.07	24.88 ± 20,.81	0.052
Aqaurel			
Chest pain	18.41 ± 9.29	20.62 ± 8.38	0.391
Dyspnea	21.29 ± 7.24	21.83 ± 6.52	0.790
Arrhythmia	11.18 ± 5.07	12.24 ± 4 43	0.444
Anxiety (Beck)	18.29 ± 13.34	19.37 ± 12.49	0.776
Depression (Zung)	39.24 ± 10.0	43.42 ± 9.07	0.137

chamber pacemakers (Tabs 2, 3). Patients with dual chamber rate-adaptive pacing showed higher scores in several SF-36 dimensions reflecting physical and mental health (MH, VT,GH, PCS, MCS). In the same way lower scores in Aquarel and lower degree of anxiety and depression was shown in DDDR pacemakers compared to DDD pacemakers (Tab. 3).

There was a strong and significant correlation between degree of anxiety and scores in SF 36 dimensions (PF -0.506, SF -0.418, RP -0.405, RE -0.451, MH -0.673, VT -0.594, BP -0.595, GH -0.469, PCS -0.630, MCS -0.708, PHS -0.436, all $p<0.001$), and scores in Aquarel (Aquarel 1 scale – chest pain 0.656, Aquarel 2 – dyspnea 0.618 and Aquarel 3 arrhythmia 0.625 all $p<0.001$)

In the same way, there was a strong and significant correlation between the degree of depression and scores in SF 36 dimensions (PF -0.515, SF -0.526, RP -0.415, RE -0.427, MH -0.574, VT -0.622, BP -0.546, GH -0.473, PCS -0.624, MCS -0.698, PHS -0.518, all $p<0.001$), and scores in Aquarel (Aquarel 1 scale – chest pain 0.617, Aquarel 2 – dyspnea 0.548 and Aquarel 3 – arrhythmia 0.498, all $p<0.001$)

Discussion

It was clearly shown that pacemaker implantation results in improvement of health-related quality of life.

The answer to the question if the pacing mode selection has an influence on the QOL is less clear. Benzer et al. reported that improved QOL after pacemaker implantation observed during 6 month follow-up period was related to clinical symptoms and ECG finding before implantation rather than pacing mode. Patients with previous syncope or dizziness experienced greater improvement of QOL than subjects presenting with palpitations. Patients with ECG diagnosis of sinus node dysfunction or atrial fibrilation improved more than patients with AV block.

There are differences in symptoms in patients with sinus nodal and atrioventricular block.

In patients with sinus node disease, an important determinant of QOL after pacemaker implantation is the presence of pacemaker syndrome. This syndrome is due to preserved ventriculoatrial conduction in single chamber pacing. Therefore, it is not surprising that worse clinical symptoms, when comparing VVI to DDD mode, were demonstrated in pacemaker patients with sinus node dysfunction.

In patients with atrioventricular conduction disturbances, a comparison of QOL between physiologic and single chamber pacing produced conflicting results. While some authors documented improved QOL with physiologic pacing other failed to confirm this.

In large prospective, randomized study PASE (Pacemaker Selection in the Elderly) no overall benefit from physiologic

Tab. 3. QOL in patients with dual chamber rate- adaptive and dual chamber non-rate- adaptive pacemakers.

	Rate-adaptive pacemakers (DDD) (n= 21)	Non-rate-adaptive pacemakers (DDDR) (n= 28)	Statistical significance (p)
SF 36			
Physical Functioning (PF)	46.19 ± 23.54	58.75 ± 21.59	0.069
Social Functioning (SF)	63.69 ± 29.02	71.88 ± 29.39	0.337
Role-Physical (RP)	46.43 ± 41.30	45.54 ± 41.42	0.941
Role-Emotional (RE)	42.86 ± 41.02	59.52 ± 42.90	0.177
Mental Health (MH)	52.76 ± 20.62	66.71 ± 17.49	0.014
Vitality (VT)	40.23 ±.16.69	55.18 ± 18.53	0.005
Bodily Pain (BP)	54.86 ± 26.63	67.75 ± 29.04	0.118
General Health (GH)	33.10 ± 24.91	44.93 ± 16.61	0.050
SF – 36 composite scores			
Change in Health (CHH)	46.43 ± 21.18	51.79 ± 16.57	0.361
Physical Component Summary (PCS)	42.96 ± 21.63	54.32 ± 16.57	0.038
Mental Component Summary (MCS)	49.32 ± 17.70	62.95 ± 15.80	0.007
Perceived Health Status (PHS)	29.76 ± 27.41	40.71 ± 24.13	0.117
Aqaurel			
Chest pain	15.46 ± 7.09	20.48 ± 8.36	0.028
Dyspnea	18.04 ± 5.27	23.95 ± 5.57	0.001
Arrhythmia	10.29 ± 4.67	12.52 ± 4.41	0.096
Anxiety (Beck)	12.86 ± 9.04	23.24 ± 14.73	0.004
Depression (Zung)	37.68 ± 7.05	42.71 ± 8.85	0.031

DDDR pacing compared to single chamber VVIR pacing was demonstrated. By subgroup analysis, only in patient with sinus node dysfunction better QOL with DDDR compared to VVIR pacing in three SF-36 subscales was demonstrated. In patients with atrioventricular block no significant differences in SF-36 subscales when compared DDDR to VVIR pacing modes were present.

In the MOST study (The Mode Selection Trial) QOL was compared between VVIR and DDDR pacing in 2010 patients with sinus node dysfunction. Significant improvement in three SF-36 subscales (role physical, role emotional and vitality) was observed. QOL was shown with DDDR pacing compared to VVIR pacing. Other parameters of SF-36 and Specific Activity Scale have not shown any benefit of DDDR over VVIR.

In the PASE and MOST only generic instruments for the assessment of QOL were used (SF-36 and Specific Activity Scale). Trends to better quality of life by DDDR compared to VVIR patients were present in above mentioned studies. In the PASE, 26 % of patients in VVIR mode were switched to DDDR mode because of symptoms due to pacemaker syndrome. It can be speculated that specific questionnaire developed for pacemaker patients would reveal differences in QOL between physiologic and non-physiologic pacing modes.

In the Canadian Trial of Physiological Pacing (CTOPP) QOL was assessed by generic tool (SF-36, Specific Activity Scale) and pacemaker patient specific tool (Quality of Life Assessment Package). QOL was assessed in 1721 patients six months after pacemaker implantation. In addition, in a substudy of 269 patients QOL was assessed at baseline (within 48 hours after pacemaker implantation) and after six months.

Of 1721 patients, 983 patients were randomized to ventricular pacing (about half of them with sensor enabled — VVIR) and 783 patients were randomized to physiologic pacing (DDD, DDDR and AAI). There were no differences at the 6-month after implantation in 1721 patients between physiologic and VVI±R pacing modes in general QOL. Pacemaker specific scale was not assessed in these patients.

In the substudy, pacemaker implantation was associated with significant improvement in general as well as pacemaker specific scale but no differences could be observed between assigned pacing modes.

Few studies comparing QOL in various physiologic pacing modes or various types of rate-adaptive pacing are available. No difference in QOL was observed in DDDR with mode switch compared to DDIR in patients with complete heart block and paroxysmal atrial tachycardia. In addition, the pacing mode had

no influence on the occurrence and duration of atrial tachycardia episodes.

The retrospective QOL analyses of MOST trial suggested that differences between various sensors used in rate-adaptive pacemakers are negligible in patients with sinus node dysfunction. Paradoxically, most sophisticated blended sensors demonstrated a trend toward worse quality of life compared to piesoelectric or accelerometer sensors.

In another study individual optimization of pacing sensor failed to improve QOL despite hemodynamic improvement (measured as maximal achieved heart rate and metabolic workload during exercise test).

Results of our study confirm the results of PASE and CTOPP trials. We were not able to demonstrate any benefit in QOL in dual chamber pacing compared to single chamber pacing. On the other hand, rate-adaptive pacing appeared to be superior to non-rate-adaptive pacing in the group of dual chamber pacemakers. In our study, the positive influence of rate adaptation on the QOL was more pronounced than the influence of AV synchrony.

Limitations of the present study are caused mainly by the relatively small number of patients included into study. In addition patients with sinus node dysfunction and AV block were evaluated together. Due to the small number of patients assigned to various pacing modes in the subgroup of sinus node dysfunction and AV block it was not possible to perform the subgroup analysis based on ECG diagnosis. However, the ratio between sinus node dysfunction and AV block diagnoses was similar in the group of single and dual chamber pacemakers. Similarly, this ratio was alike in the group of rate-adaptive and non-rate-adaptive pacemakers. Therefore it is unlikely that our results are affected by the ECG diagnosis of the patient.

In conclusion, in patients with dual chamber pacemakers rate adaptive pacing offered better QOL and more favorable psychological profile when compared to dual chamber non-rate-adaptive pacing. No significant differences in QOL and psychological profile were observed between patients with single chamber and dual chamber pacemakers. There was a strong correlation between degree of anxiety and depression and the QOL in pacemaker patients.

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SCIENTIFIC AND CLINICAL INFORMATION

High risk of infection in immunocompromised patient

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Immunodeficiency is a disorder of immune defense that predispose affected individuals to various secondary-developing defects of infectious immunity as well as malignancy. Immunosuppressed patients are at risk of developing a common bacterial, viral, as well as superficial and systemic fungal infection and parasitic infestation that may have a severe and prolonged course. Affected patients belong to a widespread group of immunosuppressive subjects as are the organ transplant recipients, patients with primary immunodeficiency disorders, HIV infection and other severe infectious and devastating disorders. Bacterial infection is common in these subjects and very often it seems to be the first clinical disturbance of immunocompromised individuals. The subjects are susceptible to repeated banal bacterial infections as folliculitis, as well as furunculosis. Erysipelas and cellulitis could be caused by less common causative agents as *Enterobacteriacae, Escherichia coli* or uncommon strains of *Streptococci, Staphylococcus aureus,* and others. The various bacteria can contribute in synergy with beta- hemolytic streptococci to the complicated course of erysipelas. The frequency of MRSA isolation suggests that beta-lactam antibiotics may not be sufficient for the treatment of bullous erysipelas (1). The viral infection as frequent herpes simplex infection could have severe clinical picture and may affect other organs then the skin. The life threatened course could be accompanied with affection of CNS. The condition could be life endangered in the case of atopic eczema (2). Severe viral infection should be treated with systemic antiviral medication. The herpes zoster infection is widespread and could be disseminated. Other common viral infection as warts, molluscum contagiosum, condylama accumnatum have severe developing with localization normally spare of these infections. Immunocompromised patients are at risk of developing a common superficial and systemic fungal infection. Yeast infection is well documented as candidiasis of intertriginous spaces in patients with diabetes mellitus and other immunocompromised patients. is a frequent causative agent. The epidemiology of causative agent is changing from *Candida albicans* to less common strains as *Candida glabrata* and *Candida krusei* (3). Common superficial fungal infection caused by dermatophytes that have been reported to invade locally in immunosuppressed patients include *Trichophyton rubrum, Microsporum audouini, Trichophyton schoenleini, Trichophyton violaceum* and *Epidermophyton floccosum* (4). With the increasing prevalence of both primary and secondary immunodeficiency, the list will be likely expanded. Dermatophytosis in immunocompromised host is more varied and often more severe than in immunocompetent host. The dermatophyte infection could affect large area of skin and could cause serious morbidity in form of generalized infection. The most common source of fungal infection is affected toenails. The clinical feature of fungal infection may be atypical and the differential diagnosis includes several inflammatory and allergic conditions. However, in patient with impaired immunity dermatophyte could give rise to deep invasion into the dermis forming dermatophyte folliculitis. Norwegian crusted scabies is seen primarily in immunocompromised patients, in subjects who present cognitive deficiency, or suffer from severe systemic disease or in persons living in unsanitary conditions. This rare type of scabies is a fulminant and highly infectious form of ordinary scabies in which numerous mites *Sarcoptes scabiei* infest epidermis. This is considered a rare affection and it presumably represents an abnormal host immune response to the organism. Crusted scabies represents a serious therapeutic problem especially in immunocompromised patients. Norwegian scabies can present atypically and mimic a range of other dermatoses (5). Scabies infection can have serious consequences if the diagnosis is missed or delayed not only from the epidemiological point of view, but also from the possibility of secondary bacterial infection that can give rise to threatening complication. The diagnosis of scabies should be always considered in the case of immunocompromised patient suffering from pruritus.

In order to prevent severe infection of various origin is the early recognition and treatment of the first clinical sings if it is necessary also with systemic therapy which is considered to be inevitable in these subjects. Search for probable bacterial, viral and fungal infection should be done routinely in immunocompromised subjects.

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