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Treatment algorithms for special cases

Özel durumlarda tedavi algoritmaları

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Abstract

Treatment of psoriasis differs in special cases such as in women who wish to become pregnant, during pregnancy and lactation, in pediatric and geriatric populations, in the presence of obesity or chronic viral diseases, and during the COVID-19 pandemic. Due to their well-known teratogenic effect, neither topical nor systemic use of retinoids is recommended in any period of pregnancy and lactation. Literature data on treatment approaches in psoriasis in children is less than in adults, and safety data usually relate to short-term use. There is a multifactorial relationship between psoriasis and obesity; response to treatment is lower in obese patients with a body mass index greater than 30. It should be noted that the elderly have comorbidities and concomitant drug use, which increases the likelihood of side effects and drug interactions of psoriasis medications. In the presence of a viral disease, many agents used in the treatment of psoriasis carry the risk of exacerbating the infection due to their immunosuppressive properties. In such a case, the option that can be considered apart from topical therapies is narrow-band phototherapy. It was observed during the COVID-19 pandemic that there had been no increase in the risk of infection-related mortality and morbidity solely due to biological therapy.
Keywords: Psoriasis, treatment, pregnancy, children, COVID-19

Öz

Psoriasis tedavisi gebe kalmak isteyen kadınlarda, gebelikte, laktasyonda, pediatrik ve geriatrik popülasyonda, obesite ya da kronik viral hastalık varlığında ve COVID-19 pandemisi sırasında özellik arz eder teratojenik etkisi iyi bilinen retinoidlerin gerek topikal gerekse sistemik kullanımı gebeliğin hiçbir döneminde ve laktasyon döneminde önerilmez. Çocuk psoriasis olgularında tedavi yaklaşımlarına yönelik literatür verileri yetişkinlere nazaran daha azdır ve güvenlik verileri sıklıkla kısa dönem kullanımına aittir. Psoriasis ile obezite arasında multifaktöriyel bir ilişki vardır ve vücut kitle indeksi 30'un üzerinde olan obez hastalarda tedaviye yanıt daha düşüktür. Yaşlıların aynı anda birden çok hastalığı ve ilaç kullanımı olduğu ve bunun da psoriasis ilaçlarının yan etkilerinin ve ilaç etkileşimlerinin görülme olasılığını artıracağı unutulmamalıdır. Kronik viral hastalık varlığında psoriasis tedavisinde kullanılan birçok ajanın immün baskılayıcı özelliğinden dolayı enfeksiyonu alevlendirme riski bulunur. Bu durumda topikal tedaviler dışında en çok tercih edilebilecek tedavi dar bant fototerapisidir. COVID-19 pandemisi sırasında psoriasis hastaların özellikle biyolojik tedaviden ötürü enfeksiyon ilişkili mortalite ve morbidite riskinde artış olmadığını gözlenmiştir.
Anahtar Kelimeler: Psoriasis, tedavi, gebelik, çocuk, COVID-19

In women intending to become pregnant at a childbearing age/during pregnancy/lactation

In women at their childbearing age who choose to not have protection and wish to become pregnant, a treatment approach similar to one used during pregnancy and lactation is recommended. The patient should be reminded that a 10-20% worsening may occur in their psoriasis during pregnancy. Similarly, a 50% flare-up may be seen in their psoriasis within the first 6 weeks after birth[1]. It should be noted that potential problems may arise against psoriasis treatment agents in these periods, and especially when a systemic treatment indication appears, potential risks should

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be explained and the treatment started after obtaining consent from the patient.

Since when conception will occur in female patients in their reproductive age who have no protection cannot be predicted and risks associated with many drugs are particularly high in the first trimester, this period should deserve special attention. Potent topical steroids and topical calcipotriol are not recommended in this period, but they can be used starting from the third trimester. Although topical absorption of calcipotriol and calcipotriene is little, there are hesitations about their use as there are no data on their safety[1,2].

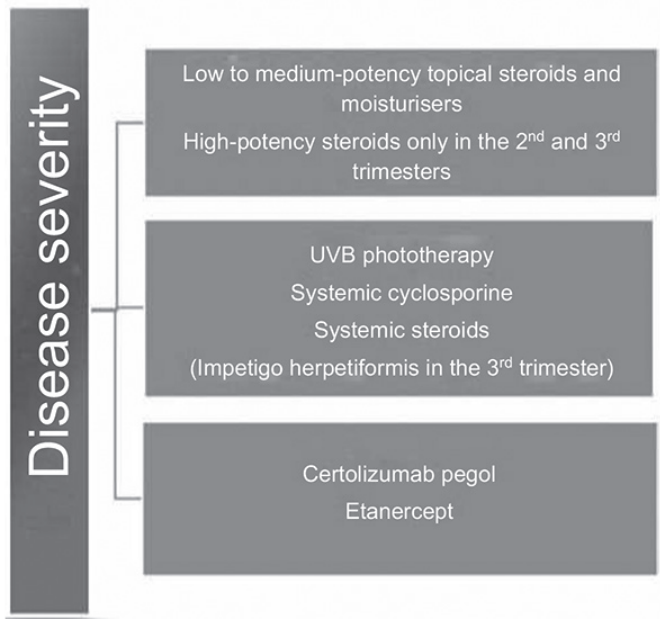
Due to their well known teratogenic effect, neither topical nor systemic use of retinoids is recommended in any period of pregnancy and lactation.

Another agent to be avoided during pregnancy and lactation is methotrexate, which is mutagenic, teratogenic and abortigenic. A psoralen ultraviolet A (PUVA) therapy should also be avoided during pregnancy and lactation due to its mutagenic potential. However, a topical PUVA therapy is argued to be relatively safer from the third trimester on[3]. The most appropriate therapy after topical treatments in these periods is the ultraviolet B (UVB) phototherapy. Systemic steroids may be used when there is no response to the UVB phototherapy, and particularly in the presence of impetigo herpetiformis, which occurs mostly in the third trimester. However, it should be borne in mind that systemic steroids may cause cleft lip/palate when used in the first trimester and low birth weight and growth/development retardation in the other periods[4]. A rebound may also occur when the treatment is discontinued[2]. When using them during lactation, breastfeeding should be avoided until 4 hours after taking the pill due to its half-life.

Although it is in pregnancy category C of the American Food and Drug Administration (FDA), cyclosporine is another option to be used in resistant cases in this period. It is not teratogenic, but has been found associated with low birth weight and prematurity in cases involving a transplant[5]. Since its rate of transmission to the milk shows variances, its use during lactation is not recommended[2].

There are different suggestions in the literature about the use of anti-tumour necrosis factors during pregnancy and lactation. Although they are in FDA pregnancy category B, there are reports stating that they may involve anomalies such as VACTERL (vertebral anomaly, anal atresia, cardiac anomalies, tracheo-oesophageal fistula, oesophageal atresia, renal anomalies, and extremity anomalies)[6,7], but sufficient data to to reach a final judgement is not available[2]. Concerns about the use of biologics relate more to the risk of infection in the infant due to placental transmission than their embryotoxicity and teratogenity[8]. Biologics in the form of monoclonal antibodies with a long half-life are known to pass through the placenta starting from week 16. Antibodies have been detected in the blood of infants within 6 months after birth. Since risk of infection has been reported in newborns with the use of this group of therapies and live vaccines in the last trimester of gestation, the vaccination protocol should be reviewed. Agents with a minimal placental transmission should be preferred in pregnancy[9,10]. Among these, certolizumab is the most widely used agent. With a lower placental transmission than adalimumab and infliximab, etanercept is a good alternative and can be used until gestational week 30. Although their FDA pregnancy category is B, ustekinumab and secukinumab have more limited data on their safety in the literature. Data on the safety of ixekizumab, brodalumab apremilast and IL-23 inhibitors in pregnancy is inadequate[11-13].

The vaccination schedule should be revised after consulting a paediatrist about live vaccines in babies born to a mother who used biologics during pregnancy[10]. Use of biological agents during lactation is agreed to be fairly safe and these antibodies are believed to be broken down with an enzymatic effect in the gastrointestinal system of the infant[12].



In paediatric psoriasis

Literature data on treatment approaches in psoriasis in children is less than in adults and safety data usually relate to short-term use[13]. In relation to the topical treatment options in paediatric patients, there are reports on the effectiveness of using tacrolimus particularly for the facial and inverse region involvements[14,15]. Although an nbUVB phototherapy is a safe option in adolescent patients, its long-term risk of carcinogenesis should not be overlooked and care should be taken when using it in light-skinned blond children[16]. Anxiety associated with the cabin environment may also pose difficulties in treatment[17]. The data on the use of antibiotics in guttate psoriasis are controversial[13].

It should be noted that a systemic acitretin therapy (0.2-0.5 mg/kg/day) that can be used in paediatric patients particularly for the pustular and erythrodermic forms of psoriasis may have a toxic effect on the skeletal system in the long-run[18]. Methotrexate in doses of 0.2-0.7 mg/kg/day has been found effective in paediatric patients[19]. Although a cyclosporine therapy (3-5 mg/kg/day) has been reported to be effective and safe in paediatric patients up to a year, its level of evidence is not sufficient[20]. Although none of the conventional systemic therapies are approved for the paediatric psoriasis patients, they are used in short-term and intermittent treatments. For example, more than 80% of the patients discontinue their methotrexate therapy after two years due to its side effects.

Among anti-tumour necrosis factor agents, etanercept has the broadest body of evidence in patients resistant to other therapies and it has been reportedly effective in the short-term in doses of 0.8 mg/kg/week in

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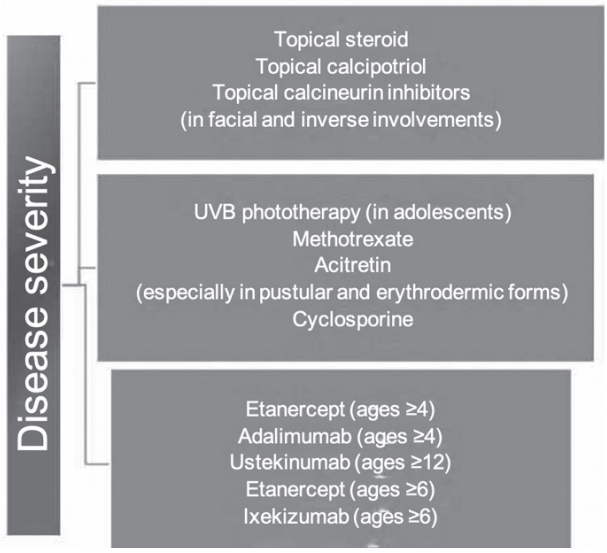
children older than 4 years and even has been used safely for up to 8 years in patients with rheumatoid arthritis[21,22]. The European Medicines Agency approved adalimumab in 2015 for the treatment of paediatric patients aged 4 and over with moderate psoriasis[23] and it was found quite effective in doses of 0.8 mg/kg (maximum: 40 mg) at week 16. In adolescents aged 12 and over, ustekinumab is recommended in posologies of 0.75 mg/kg for up to 60 kg, 45 mg for up to 100 kg, and 90 mg for over 100 kg[10-12]. Secukinumab was also approved by the European Union very recently for paediatric psoriasis patients aged 6 and over in doses of 75 mg for <50 kg and 150 mg for >50 kg. Again recently, ixekizumab was approved by FDA to be used in paediatric psoriasis patients aged 6 and over (40 mg initial dose and 20 mg maintenance for <25 kg, 80 mg initial dose and 40 mg maintenance for 25-50 kg, and 80 mg initial dose and 160 mg maintenance for >50 kg).

Studies on paediatric use of the other biological agents have not been completed yet[24]. The treatment scheme for biologics is similar to that of adults and screening tests are recommended as in adults, but care should be taken in this age group in relation to vaccination protocols and particularly to scheduling of live vaccines.



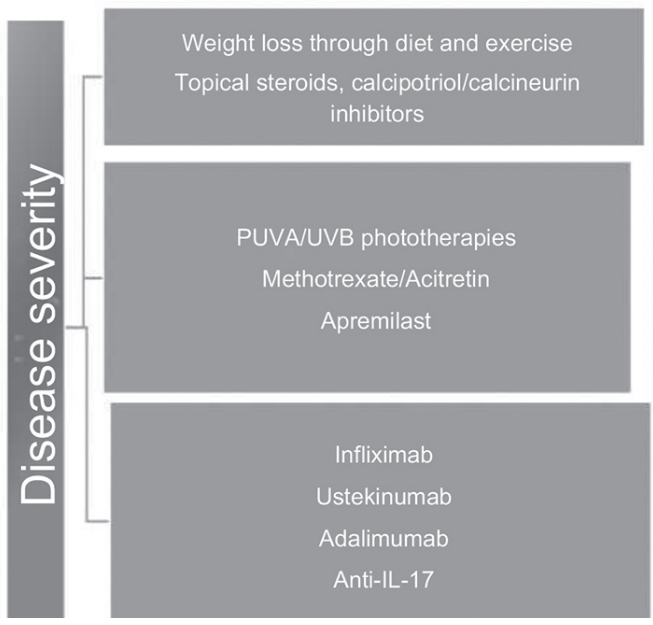
In obese patients

There is a multifactorial relationship between psoriasis and obesity; obese patients with a body mass index greater than 30 respond less to treatment[25]. Drug-related side effects are also seen more in obese patients. In obese patients, no decline in efficacy is expected with agents that can be adjusted for weight (e.g. methoxypsoralen, infliximab). A low-calorie diet for 4 weeks alone showed a decrease in psoriasis symptoms in obese patients[26]. Therefore, before starting treatment, healthy eating, exercise and even diet should be recommended for obese patients.

In the management of psoriasis, acitretin remains of limited effect due to elevated lipid levels, methotrexate due to increased risk of hepatotoxicity and cyclosporine due to increased risk of nephrotoxicity. In obese psoriasis patients who receive a methotrexate therapy, the risk of hepatosteatosis, and if accompanied by diabetes, the risk of liver cirrhosis increases[27,28]. For this reason, methotrexate using patients who are both obese and have accompanying diabetes should be monitored carefully and administered an early liver biopsy without waiting for the cumulative dose[25]. The dose in a cyclosporine therapy is calculated based on the ideal weight, but depending on the length of treatment and dosage, the risk of nephrotoxicity increases and other side effects such as hypercholesterolaemia and hypertriglyceridaemia may also occur[29].

Patients may gain weight between 1.5 and 2.5 kg during an anti tumour necrosis factor (TNF) therapy without a known reason, but this does not hinder the use of anti-TNF therapies[30]. Literature data and experiences show that use of fixed-dose biologics produces better clinical responses in those with an ideal weight or are overweight than in morbid obese. It has been shown that with an infliximab therapy, in which the dose can be adjusted for weight, there was no change in efficacy in obese patients[31], but with adalimumab, which is administered in fixed doses, a significant decline in efficacy was observed[32]. Since two different doses are used in an ustekinumab therapy depending on the weight, any change in efficacy is not obvious[33]. In an etanercept therapy, a slight decrease in efficacy has been seen in obese patients[34,35]. No significant loss of efficacy has been observed also in patients using anti-IL-17 agents[10]. Literature data on IL-23 inhibitors is not available yet.

Although it has no indication in our country, apremilast, unlike biologics, has caused 5-10% weight loss in 12% of those using it in the studies and it can be preferable for obese patients.

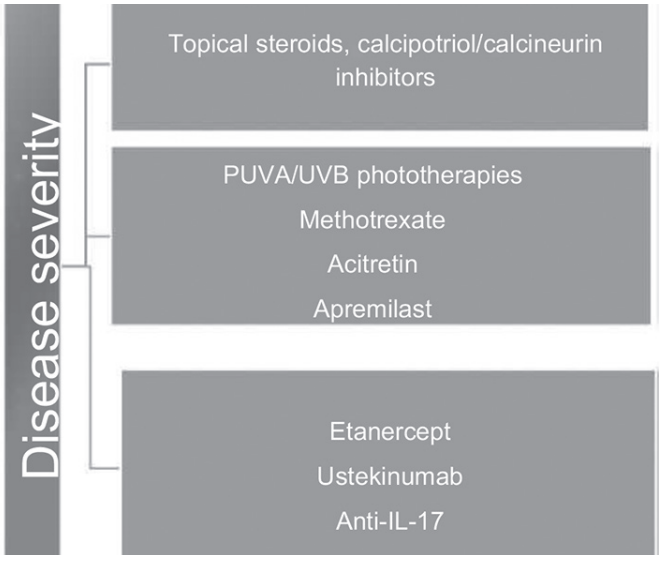


In older patients

Treatment of psoriasis in the elderly poses potential problems. Itching and dryness in aged skin carries the risk of disease koebnerization[36]. To be able to treat this group of patients, age-associated changes should be known well. For example, older people have more than one disease and drug use at the same time and this increases the likelihood of side effects and drug interactions[37]. In old age, the functional capacity of many organs decrease and while their water content declines, their fat content goes up[38,39]. The most important pharmacokinetic change in old age is the decline in the elimination capacity of kidneys[40]. In that

sense, older patients may be considered to have a renal failure. For this reason, dose adjustments in the elderly should be individually tailored; any dose increase should start with a low dose and side effects should be monitored while gradually increasing the dose. Although topical therapies are preferred in the elderly to avoid systemic side effects, difficulty in administration and cutaneous side effects may challenge patient compliance[41].

Although acitretin causes hypertriglyceridemia and dry skin, it is a suitable treatment option for the elderly. Due to decline in renal functions, the dose should be kept lower when administering a methotrexate therapy, keeping in mind that there may also be an increase in the risk of myelosuppression. However, methotrexate has been shown to have positive effects on cardiovascular comorbidities[37,38]. Cyclosporine use in the elderly may pose important problems including hypertension, renal dysfunction and drug interactions. Considering the decrease in renal functions, glomerular filtration rates should be checked in this patient group before starting the treatment, and if impaired, it is not recommended to start the treatment[41,42]. In patients with organ failures and comorbidities, apremilast is one of the agents that can be used before starting a biological therapy. When compared to adults, no increase in adverse events such as infection and malignancy has been seen in older patients receiving biological therapies[43]. However, from anti-TNF agents, etanercept, which has a shorter half-life, may be the first option for the elderly due to more frequent comorbidities, immune ageing and impaired cognitive functions along with increased risk of infections, and traumas such as operations experienced in this patient group. IL-12/23 and IL-17 inhibitors may be the agents to be considered after etanercept due to their safety profiles[44].

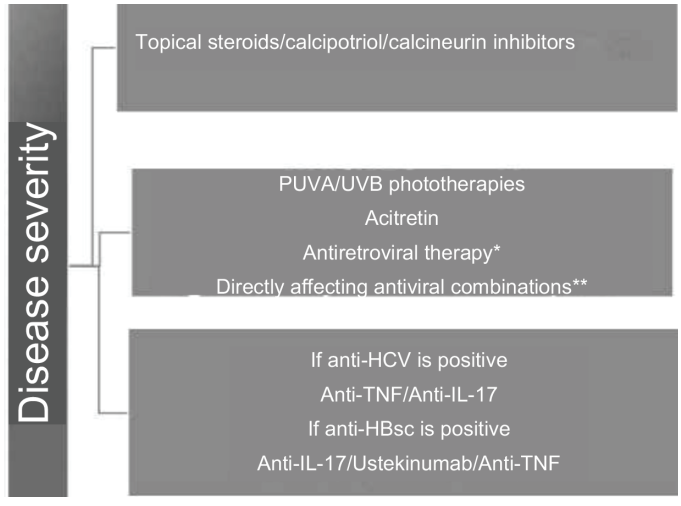


In viral infections

Treatment for psoriasis remains limited in the presence of chronic viral diseases. Due to their immunosuppressive property, many agents used in the treatment of psoriasis carry the risk of exacerbating infection and leading to opportunistic infections in the presence of a human immunodeficiency virus (HIV) infection. Additionally, psoriasis occurring during an HIV infection is resistant to conventional therapies[45]. In this case, the option that can be considered outside topical therapies is the narrow-band phototherapy. The psoralen ultraviolet A therapy can be used with minimal hepatotoxicity up to a year during a hepatitis C infection[46]. As improvements have been observed in the psoriasis conditions of HIV patients receiving an antiretroviral therapy alone, its use is recommended even in HIV patients whose CD4 level is not below 350/mm^3[47-49]. Acitretin is primarily preferred in patients needing a systemic therapy as it has no immunosuppressive property and no significant hepatotoxicity has been observed in patients with chronic hepatitis who used it in the long-term[50]. In selected HIV patients who are resistant to acitretin, conventional or biological agents alongside an antiretroviral therapy may be tried, but they must be used under close monitoring and only after the approval of an infectious diseases specialist[45,51].

In patients with chronic hepatitis infection, methotrexate is absolutely contraindicated due to hapatotoxicity and mycophenolate mofetil due to immunosuppression, and cyclosporine is relatively contraindicated[52]. A prophylactic lamivudine therapy in hepatitis B carriers may suppress reactivation of the virus. For this reason, a lamivudine therapy should be initiated 2-4 weeks before starting any immunesuppressor or biologic and continued until 3-6 months after the treatment[53]. The risk of reactivation is low in a kor antigen positivity alone and a transition to a biological therapy with or without antiviral protection can be made after checking the viral load and consulting a gastroenterology specialist[10,11].

Although anti-IL-17 inhibitors seem safe during a hepatitis C infection, there is not sufficient data. If possible, a hepatitis C therapy should be administered first and then the biological therapy started[10]. There are contradicting results in relation to hepatitis B or C activation with the use of ustekinumab[54].



*In HIV positive patients, **In HCV positive patients

During COVID-19 pandemic

Although it is still early to clearly determine if patients with psoriasis have a tendency to contract COVID-19 infection, data collected from registry systems and case reports on the progression of chronic immune-mediated diseases show that there is no increased risk of infection-related mortality and morbidity due to a biological therapy on its own[55-58]. Since poor prognostic factors for COVID-19 infection such

as diabetes, obesity, old age, male gender and cardiovascular diseases are also the conditions that may accompany psoriasis patients, any patient eligible for a systemic therapy should be assessed individually also taking their comorbidities into consideration. Every patient is recommended to receive training in social distancing, mask wearing and rules of hygiene. Unless a suspicious anamnesis or clinical finding is present before starting the treatment, routine pcr or antibody testing for COVID-19 is not recommended for every patient. From conventional agents, acitretin and apremilast, which has no indication in our country yet, are safer options for not causing immune suppression[57,58]. Although there are no apparent differences among biologics in relation to their safety data, some authors primarily prefer IL-17 and IL-23 inhibitors, the latter of which is still not available in our country[58].

General approach is that since uncontrolled active psoriasis can involve dramatic consequences in the period of pandemic, treatment should not be suspended especially in patients taking biological agents, but the drug dose may be reduced or the treatment suspended in patients who are on a conventional therapy, which carry a higher risk of infection, in consideration of the current status and prognosis of the disease.

In psoriasis patients who contracted the COVID-19 infection, it would be appropriate to suspend systemic treatments and restart psoriasis treatment 2-4 weeks after they recover from the infection[59,60].

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