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刘志红院士主持的全国多中心临床研究成果在国际著名期刊发表

刘志红院士主持的全国多中心临床研究成果在国际著名期刊《Annals of Internal Medicine》发表

2014年11月11日，由国家肾脏疾病临床医学研究中心刘志红院士牵头主持的“狼疮性肾炎的多靶点诱导治疗多中心研究”成果在国际著名医学杂志《Annals of Internal Medicine》（影响因子16.1）在线发表，题目为“ Multitarget Therapy for Induction Treatment of Lupus Nephritis: A Randomized, Controlled Trial ”，对于我国狼疮性肾炎（LN）患者采用多靶点疗法（激素+他克莫司+霉酚酸酯）诱导治疗，与静脉环磷酰胺相比，可获得更高的完全缓解率，且不增加不良事件发生风险。研究成果反映了该领域近年来的重大进展，是一项具有标志性的研究成果。文章在线发表后受到国际肾脏病界和风湿病界的高度关注。《Nature Review Nephrology》第一时间以“Research Highlights”对其进行了报道；《Rheumatology News》也对文章进行了报道和评价，多个国际学术网站对本文做出了报道。

RESEARCH HIGHLIGHTS

LUPUS NEPHRITIS

Multitarget induction therapy for LN

Multitarget therapy should be considered as an alternative to conventional therapy for induction treatment of lupus nephritis (LN), say the researchers of a new study. Zhi-Hong Liu and colleagues found that patients who received multitarget therapy, comprising mycophenolate mofetil (MMF), tacrolimus and steroids, were more likely than those who received conventional therapy, comprising intravenous cyclophosphamide and steroids, to achieve complete remission, with similar incidences of adverse events between the two groups.

Given the fundamental role of immune dysregulation in the pathogenesis of LN, Liu and colleagues hypothesized that targeting multiple aspects of the immune response with combined immunosuppressants might improve outcomes for affected patients. An earlier pilot study indicated that a multitarget regimen was more likely than conventional therapy to induce remission in patients with concurrent class IV and V LN. To further assess the efficacy and safety of this multitarget induction regimen, the researchers performed a randomized open-label trial across 26 renal centres in China.

After 24 weeks of therapy, significantly more patients on multitarget therapy than on conventional therapy achieved complete remission (45.9% versus 25.6%, P <0.001). Overall response (complete and partial remission) was also higher in the multitarget therapy group than in the conventional treatment group (83.5% versus 63.0%, P <0.001), and the median time to overall response was shorter in the multitarget group (8.9 weeks versus 13.0 weeks). On the basis of their findings, the researchers support use of the multitarget approach for induction treatment of LN.

Susan J. Allison

Original article Liu, Z.-H. *et al.* Multitarget therapy for induction treatment of lupus nephritis. *Ann. Intern. Med.*

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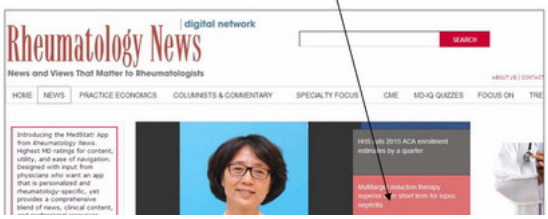

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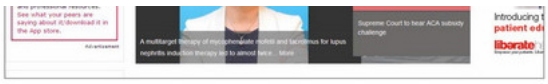

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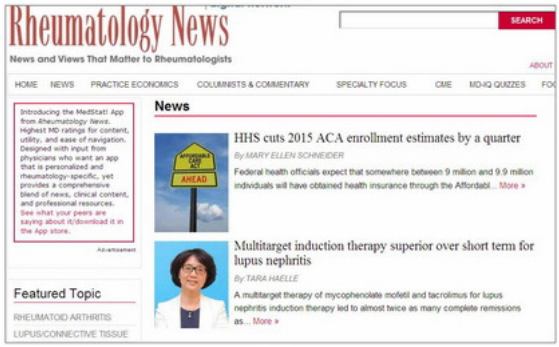

具体内容

News

therapy superior over short term for lupus nephritis

By: TARA HAELLE, Rheumatology News Digital Network
November 10, 2014

FROM ANNALS OF INTERNAL MEDICINE

VITALS

Key clinical point: Multitarget treatment is superior to intravenous cyclophosphamide as induction therapy for lupus nephritis.

Major finding: Among of patients receiving mycophenolate mofetil and tacrolimus, 45.9% achieved complete remission, compared with 25.6% receiving IV cyclophosphamide ($P < .001$).

Data source: A 24-week, open-label, randomized, controlled trial of 368 adults from 26 centers in China between April 2009 and June 2011.

Disclosures: The National Basic Research Program of China and the National Key Technology R&D Programs funded the study. Information on disclosures was unavailable at the time of publication.

A multitarget therapy of mycophenolate mofetil and tacrolimus for lupus nephritis induction therapy led to almost twice as many complete remissions as did intravenous cyclophosphamide in an open-label, randomized, controlled trial.

"Because immune dysregulation is fundamental to pathogenesis of lupus nephritis, with both B and T cells involved in the development of the disease, it may be necessary to target multiple aspects of the immune response using combined immunosuppressants," wrote Dr. Zhi-Hong Liu of Nanjing (China) University and her colleagues (Ann. Intern. Med. 2014 Nov. 11 [doi:10.7326/M14-1030]).

Between April 2009 and June 2011, 368 adults aged 18-65 years from 26 renal centers in China were randomized to receive mycophenolate mofetil (MMF) and tacrolimus with a steroid or IV cyclophosphamide with a steroid for 24 weeks. A total of 362 received medication (6 did not receive their assigned cyclophosphamide treatment for unknown reasons), and 310 completed the whole 24-week course of treatment. All participants in the study had biopsy-proven lupus nephritis diagnosed within the previous 6 months and had not been

Zhihong Liu

previously treated with MMF, cyclophosphamide, tacrolimus, or high-dose methylprednisolone, nor had they had renal replacement therapy, plasmapheresis, or IV gamma globulin therapy in the previous 12 weeks.

All patients began by receiving IV methylprednisolone pulse therapy (0.5 g/day) for 3 days and then oral prednisone (0.6 mg/kg) daily for 4 weeks, with prednisone tapering to 10 mg/day for the remainder of the study period. Following methylprednisolone pulse therapy, the multitarget group received MMF (0.5 g twice daily) and tacrolimus (2 mg twice daily) while the comparison group received IV cyclophosphamide (initially 0.75 g/m^2 body surface area, then adjusted to 0.5-1.0 g/m^2).

Nearly half – 45.9% – of patients in the multitarget group achieved full remission, whereas 25.6% of patients receiving IV cyclophosphamide showed complete remission ($P < .001$). The investigators defined complete remission as a 24-hour urinary protein excretion of 0.4 g or less, the absence of active urine sediments, a serum albumin level of 35 g/L or greater, and normal serum creatinine.

Results on secondary endpoints also favored multitarget therapy. The percentage of patients who had an overall response to treatment (complete and partial remissions) was 83.5% for multitarget therapy and 63% for cyclophosphamide ($P < .001$). Multitarget therapy patients responded to treatment at a median of 8.9 weeks, compared with cyclophosphamide-treated patients at 13 weeks. The investigators defined partial response as a 50% or greater reduction in proteinuria and urine protein less than 3.5 g/24 hours, a serum albumin level of 30 g/L or higher, and a normal or 25% or lower increase in serum creatinine level from baseline.

After treatment, patients in the multitarget therapy group also had significantly better results on other secondary endpoints, including changes in urine protein, serum albumin, systemic lupus erythematosus disease activity score, and C3 levels.

Adverse events occurred among 50.3% of multitarget recipients and 52.5% of cyclophosphamide recipients. More patients who received multitarget therapy had a serious adverse event (7.2% vs. 2.8%, respectively), and more patients withdrew from the multitarget therapy group (5.5% vs. 1.7%), but there were no statistically significant differences between the groups for either comparison.

The study was supported by the National Basic Research Program of China and the National Key Technology R&D Programs. Information on disclosures was unavailable at the time of publication.