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Rituximab in Systemic Lupus Erythematosus: An Evidence Based Case Report

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Introduction: Systemic Lupus Erythematosus (SLE) is an autoimmune disease which may cause mortality and morbidity. Therefore, a good management should be done to improve patient outcome. There have been a lot of drug used to control the disease, however their usage are still controversy. Rituximab, which target B cells, shows a promising outcome but further evaluation is needed. The aim of this evidence based case report (EBCR) is to know the efficacy of rituximab as an additional treatment in SLE patients. Methods: Literature searching was conducted in PubMed, Science Direct, Google Scholar and Cochrane Library to find the available evidence. After finding the evidence needed, we evaluate the evidence by using critical appraisal questionnaire from Oxford Center of Evidence-Based Medicine and compare the validity and relevance criteria of each articles. Results: From four databases, four articles were selected for further appraisal. Those articles included one systematic review, one randomized clinical trial and two prospective study. Rituximab in addition to standard therapy showed a clinically higher response compare to standard therapy with response varied from 57–100% compare to standard therapy (varied from 45.9–92.8%). However, when measured statistically, there were no statistically significant (p > 0.05) difference between addition of rituximab group and standard treatment. Conclusion: Rituximab as an additional treatment may be clinically effective in improving SLE patients’ outcome and safe to be used in SLE management.

Keywords: Rituximab, Systemic Lupus Erythematosus, Treatment.

1. INTRODUCTION

Systemic Lupus Erythematosus (SLE) is an autoimmune disease which affects 20 to 150 people per 100,000 population with 90% cases occur in women especially women in childbearing age.1,2 In Indonesia, based on epidemiology study in Rheumatology Clinic, Department of Internal Medicine, Cipto Mangunkusumo Hospital (CMHI), there were 1.4% cases of SLE on 2002. Other study in Hasan Sadikin Hospital, Bandung, Indonesia, showed that there were 291 patients or 10.5% of SLE patient came to Rheumatology Clinic in 2010. From these data, we could say that the prevalence and incidence of SLE were varied among places but the data in Indonesia show an increasing trend from 2002 to 2010.3

Beside its prevalence, SLE had a higher mortality and morbidity rate compare to general population. Even though the survival rate of SLE patients (88% patient survived in 5-year observation) look promising, the mortality rate of SLE patients were five times more than general population. Due to its high burden, there should be a good management to improve SLE patients’ clinical outcome and control the disease.2,3 Based on current guideline, the standard therapy of SLE are glucocorticoids, antimalarials and immunosuppressant or cytotoxic drugs. However, the efficacy of those drugs are still controversy due to their contribution to organ damage beside of their efficacy.3–5 Recent advances show that B cells play an important role in SLE pathogenesis. Self-antibody produced by B cells will stimulate the production of cytokines, complement activation and immune complex formation that may result in inflammation, tissue damage and other clinical manifestation.6,7 Because of its role, inhibiting or targeting B cells may result in reduction of SLE disease progression.

One of the drug which target B cells is a chimeric monoclonal antibody drug, Rituximab (RTX). Its role in targeting CD20 protein on B cells’ membrane shows a promising outcome in SLE management. Some trials show that rituximab has a good efficacy in treatment of SLE, however some others failed to demonstrate the same outcome. Because of those controversies, further evaluation about efficacy of rituximab is needed. This article aims to present an evidence based case report on the efficacy of rituximab as an additional therapy in SLE patients’ management.7

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1.1. Clinical Scenario

A patient, woman, 18 years old enter the ward from Emergency Room with diagnosis of Acute Respiratory Distress Syndrome (ARDS), sepsis, miliary tuberculosis on oral anti-tuberculosis drug, acute diarrhea with mild-moderate dehydration. Systemic Lupus Erythematosus (SLE) with hematology and musculoskeletal involvement, hepatomegaly with elevated transaminase enzyme, hypoaalbuminemia, hyponatremia, thrombocytopenia, hypokalemia dan kyphosis. All other problems but Systemic Lupus Erythematosus (SLE) were managed and patient seem to have an improvement. After further assessment, this patient was given high dose methylprednisolone (corticosteroid) as a standard therapy for SLE and planned to be given treatment according to the current guideline in Indonesia which use glucocorticoids combined with immunosuppressant or anti-malarials, however the doctor wonder whether the addition of recent advances of using B-cell depletion therapy (Rituximab) to standard therapy may show a better clinical or laboratory outcome in this patient.

1.2. Clinical Question

In patient with systemic lupus erythematosus, does rituximab compare to standard therapy may improve clinical or laboratory outcome of the patient?

2. METHODS

This evidence based case report used four databases for literature searching. Those databases were PubMed, Science Direct, Google Scholar and Cochrane Library. Literature searching was conducted on November 8th 2015 by using keywords as follows: (Systemic Lupus Erythematosus OR SLE OR lupus) AND (Rituximab OR RTX). Addition of keywords such as “Randomised clinical trial” or “Systematic review” or “Meta-analysis” was included if the databases didn’t have those study limitation option (Table 1).

The inclusion criteria used in this report were study on human, using English or Indonesian language in the article, clinical study, systematic review and meta-analysis. The exclusion criteria in this report were no full text availability, no corticosteroid or other standard therapy as a comparison in the study and guideline.

After searching journals, we screen the articles and filter them based on inclusion and exclusion criteria, then we did an in depth screening to find the suitable articles. Besides, we double filter the suitable articles from one journals with the articles found in another journals. Finally, we get the articles which will be appraised by using critical appraisal questionnaire from Oxford Centre for Evidence-Based Medicine. Besides, level of evidence in each journals was also measured by using “Oxford Center for Evidence Medicine 2011 Level of Evidence.” We appraised the articles based on validity, importance and relevance criteria to find the best recommendation for our clinical question.

3. RESULTS

After searching in PubMed, Science Direct, Google Scholar and Cochrane Library by using selected keywords, we found 1,219 articles. However, only 16 articles from PubMed (10 original articles and 6 systematic review/meta-analysis) and 7 articles from Google Scholar (5 original articles and 2 systematic review/meta-analysis) were selected from title and abstract screening. From those 23 articles, there were same articles found in both database and one article in German so further filter was applied. Out of 18 articles, only 4 articles were selected for critical appraisal, the rest were excluded due to not using corticosteroid or standard therapy as comparison. For systematic review/meta-analysis, only latest article was selected for critical appraisal. Those articles, which included one systematic review, one randomized clinical trial and two prospective study, were articles from Rovin et al., Moroni and Raffiotta et al., Moroni and Galfetti et al. and Cobo-Ibanez et al. Level of evidence in these studies range from level 1 to level 3 based from Oxford Level of Evidence 2011.4-10,12

All but one systematic review discuss about renal response after 12 months of follow up while Cobo-Ibanez et al. measure the efficacy of rituximab in treatment of non-renal manifestation of SLE. The number of samples used in these studies varied from 24 to 1,231 patients. Furthermore, most studies used class III-IV (±class V) lupus nephritis as its samples.4,10-12  Three of four studies (two prospective study and one randomized clinical trial) showed that there was no statistically significant difference between rituximab and other drugs in the treatment of SLE. However, if renal response were being compared clinically, there were higher response in rituximab group compare to other groups. In study conducted by Rovin et al., renal response was found in 57% of rituximab treated compared to placebo group (45.9%). Same result also seen in study conducted by Moroni and Raffiotta et al. where rituximab renal response after 12 months of observation were 100% compare to cyclophosphamide and mycophenolate mofetil which had 91.9% total renal response rate. Moroni and Galfetti et al. also had a similar result in which 100% renal response was found in rituximab group while 92.8% renal response was found in cyclophosphamide user.10-12  In systematic review done by Cobo-Ibanez et al., there were various results on the efficacy of rituximab in extra-renal SLE treatment. One randomized clinical trial showed no clinically or statistically significant difference in the usage of rituximab. While other study showed a statistically and clinically significant improvement on disease activity in short and long term follow up.4

4. DISCUSSION

Multiple factors are involved in pathogenesis of SLE, from hereditary factors to environmental factors such as Epstein-Barr virus, UV light and drug interventions. All of those factors will trigger innate and adaptive immune response and result in the collection of apoptotic nuclear fragments, including double and single stranded DNAs, RNA binding nuclear and non-nuclear antigens. Those apoptotic fragments will be processed by Antigen Presenting Cells (APC) like B cells or plasmacytoid dendritic cells and presented to T cells. After sensing the presence of APC, those T cells will trigger B-cells to produce self-antibody towards the APC and enhance APC immune response. In addition, cytokines also released from APC and activated more immune response from auto-B cell and auto-T cell. As the result, those autoimmune will form an antibody-antigen immune complexes and inflammation occur. From here, we can see that B cells play an important role in SLE pathogenesis. By inhibiting B cells, like what rituximab does, the progression of SLE may be ceased.6

From four journals appraised in this EBCR, we could see that all of the journals had the same relevance criteria with clinical
question. However, from the validity criteria, only Rovin et al. fulfill almost all aspect needed for a good therapeutic research although they didn’t mention about concealment process during randomization. Other research done by Moroni and Raffiotta et al. and Moroni and Galleli et al. didn’t do a randomization and blinding in applying the intervention (rituximab) thus it may cause a bias on the result of their study. Moreover, study by Rovin et al. had more samples compare to two other original research.6–11

Table I. Summary of all studies.

<table>
<thead>
<tr>
<th>Author</th>
<th>Aim</th>
<th>Primary endpoint</th>
<th>Study design</th>
<th>Samples</th>
<th>Result</th>
<th>Summary</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rovin et al.</td>
<td>To know whether the addition of rituximab to mycophenolate methyl (MMF) and corticosteroids may improve renal response rates.</td>
<td>Renal response after 52 weeks.</td>
<td>Randomized clinical trial.</td>
<td>144 patients with class III-IV (+ class V) LN.</td>
<td>Renal response rate were not statistically significant between rituximab and placebo groups (P = 0.55). In comparison between rituximab and placebo groups, CRR (26.4% and 30.6%), PRR (30.6% and 19.3%).</td>
<td>There is no statistically difference between rituximab as an additional therapy and using MMF plus corticosteroids alone in SLE patients. However, clinically, rituximab may show an additional effect on SLE therapy.</td>
<td>2</td>
</tr>
<tr>
<td>Moroni and Raffiotta et al.</td>
<td>To compare the efficacy of rituximab, cyclophosphamide (CYC) and MMF in patient with active lupus nephritis.</td>
<td>Renal response at 3 months and complete renal remission at 12 months.</td>
<td>Prospective cohort study.</td>
<td>54 patients with active LN (class III-IV ± class V).</td>
<td>Renal response at three months: RTX versus CYC (58.8% vs. 63.1% vs. 64.7%). Complete renal remission in 12 months: RTX versus CYC versus MMF (29.4% vs. 25% vs. 41.1%).</td>
<td>In active LN treatment, RTX was at least as effective as MMF and CYC.</td>
<td>3</td>
</tr>
<tr>
<td>Moroni and Galleli et al.</td>
<td>To compare the efficacy of RTX and CYC in treatment of relapses in Proliferative LN (PLN) patients.</td>
<td>Renal remission in 12 months.</td>
<td>Prospective cohort study.</td>
<td>24 LN patients (class III-IV ± class V).</td>
<td>Renal response in 12 months: Complete renal remission: RTX versus CYC (90% vs. 71.4%). Partial renal remission: RTX versus CYC (10% vs. 21.4%).</td>
<td>In inducing remission of relapses in PLN patients, RTX was at least as effective as CYC.</td>
<td>3</td>
</tr>
<tr>
<td>Cobo-Ibanez et al.</td>
<td>To review the efficacy and safety of rituximab in the treatment of non-renal manifestation of SLE systematically from the available articles.</td>
<td>Global disease activity (complete/partial response) and adverse effect of drug.</td>
<td>Systematic review.</td>
<td>26 studies, up to 1,231 patients.</td>
<td>There were 26 studies included in this systematic review which consist of 1 RCT, 2 open-label studies and 22 cohort studies. From 1 RCT, there were no statistically and clinically significant after 52 weeks of rituximab administration. One open label and 12 cohort show a short-term statistically improvement in disease activity after 3–5 months of follow up (64.2–90.9% complete/partial response rate). In long term outcomes (more than 12 months), complete or partial response/remission rate was 7–100%.</td>
<td>In short-term treatment of non-renal SLE, rituximab could be considered as a safe and effective treatment. However, high-quality long term studies are needed especially about relapses rate after usage of RTX.</td>
<td>1</td>
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On the other hand, the systematic review done by Cobo-Ibanez et al. also had a good validity. They clearly stated the aim of their research in their paper. Moreover, they also had various resources analyzed in their paper, which can be seen from online resources and hand searching they mention in the article. In their paper, they also mention about inclusion criteria of their paper and how they measure the level of evidence from each research included in their study. Thus, this is a good systematic review. In comparison of all four journals included in this EBCR, Cobo-Ibanez et al. is the best available evidence to answer the clinical question about the efficacy of rituximab in treatment of SLE. Although Rovin et al. and Cobo-Ibanez et al. had all the validity criteria fulfilled, because Rovin et al. is a RCT which has a level of evidence 2, it is inferior to Cobo-Ibanez with level of evidence 1 as a systematic review. Nevertheless, all of four journals showed the same conclusion, in which rituximab may be used as an additional therapy to standard treatment. From Cobo-Ibanez et al., we could see that in 3 to 12 months of follow up, rituximab could consider as an effective treatment for SLE. After 3–9 months of follow up, we could see that there was a statistical improvement in disease activity (64.2–90.9%) in rituximab treated group. Moreover, after 12 months of follow up, we could also see an improvement of disease activity in which there was 70–100% complete/partial response rate in rituximab patients. By using rituximab, the dosage of steroid can be reduced, thus rituximab may be used as steroid-sparing drug in SLE treatment. Besides their efficacy, rituximab also considered safe to be used in SLE patients. The side effects which shown by rituximab compare to placebo were infusion reactions, herpes infections and neutropenia. However, because most of the research only had around 12 months of follow up, further long term side effects should be studied.

Overall, even though rituximab is safe and may be used as an additional therapy or steroid-sparing drug in SLE treatment, further research, especially RCT is needed to know the efficacy and long term safety. From all studies, there were various treatment protocol and criteria in measuring SLE treatment outcome, thus a standardized internationally accepted treatment protocol and outcome measurement criteria should be made in SLE management. Besides, there were no journals which compare every treatment options in SLE thus a bigger trial should be done to know whether the addition of rituximab compare to MMF, CYC and other treatments may show an additional effect to corticosteroids as standard treatment. Furthermore, the cost of rituximab is quite high compare to other drugs, in which each administration may cause around 25–30 million rupiah. Thus, patient preferences should be considered in using rituximab as an additional therapy for SLE.

5. CONCLUSION

Rituximab as an additional treatment may be clinically effective in improving SLE patients’ clinical or laboratory outcome. It is also safe to be used in short to medium term SLE management. Further research is needed to know the efficacy and long term effect of rituximab.

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