Low influenza vaccination rate among patients with systemic sclerosis

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Abstract

Objective. To evaluate the influenza vaccination rate and factors influencing it in patients with SSc.

Methods. A total of 177 SSc patients fulfilling the ACR and/or LeRoy and Medsger criteria were evaluated during annual meetings of the French patient association in 2006 (n=71) and 2007 (n=70) or during hospitalization in the Internal Medicine Department of Cochin Hospital in 2007 (n=36). Information on influenza vaccination was collected by a standardized form.

Results. Mean (s.d.) age and disease duration were 58.7 (12.6) and 10.5 (9.5) years, respectively. Overall, 69 (39%) patients received an influenza vaccination during the previous year. Among the 108 patients who were not vaccinated, 78 (72.2%) presented at least one indication for vaccination. The most frequent reasons for non-vaccination were absence of physician recommendation and fear of side effects. Patients who were and were not vaccinated did not differ in anxiety, depression, global disability or quality of life. Vaccination rate was significantly higher (59%) for patients who remembered receiving a letter from the French National Health Insurance Agency encouraging vaccination than among those who did not (26%, \( P=0.0001 \)). Multivariate analysis revealed the year of the last vaccination and age as two independent parameters associated with vaccination.

Conclusions. Influenza vaccination coverage is low in SSc patients. Lack of information and fear of adverse effects are the most common reasons for non-vaccination. Efforts are needed to increase the influenza vaccination coverage in this population.

Key words: Systemic sclerosis, Influenza, Vaccination, Coverage, Secondary immune deficiency.

Introduction

SSc is a CTD characterized by excessive collagen deposition and by vascular hyper-reactivity and obliterator microvascular phenomena [1, 2]. SSc is classified according to the extent of skin involvement: limited SSc (lSSc), with no detectable skin involvement [3]; lcSSc [4], with skin involvement essentially limited to the hands and face; and dSSc, with skin involvement proximal to the elbows and knees [4] and frequent visceral involvement, responsible for reduced life expectancy [7–9]. Interstitial lung disease (ILD) occurs in 16–100% of SSc patients [10, 11], with systematic evaluation revealing \( \sim 75\% \) of patients with ILD [12]. Pulmonary arterial hypertension (PAH) is a frequent complication of SSc, with a prevalence of 8–12% [6]. During the past 20 years, the frequency of deaths due to renal crisis fell substantially, while the leading causes of death in SSc were pulmonary fibrosis and PAH [13–15]. Various therapeutic strategies have been proposed for SSc, including vasodilators, anti-fibrotic agents, immuno-suppressants (ISs) and corticosteroids (CSs).

Influenza vaccination (‘flu shot’) has been shown to prevent all-cause deaths and hospitalizations during influenza
epidemics among people with high-risk medical conditions [16]. An annual flu shot is recommended for adults with high-risk medical conditions, including those with drug-induced immunosuppression [17, 18]. Therefore, an annual flu shot could be of interest for all patients with SSc because of the frequent development of severe visceral involvement, including PAH, ILD and/or renal insufficiency [10] and because ISs are widely used to treat SSc [19, 20]. Furthermore, the flu shot is safe, does not affect the clinical course and immunological parameters of scleroderma and was found to be immunogenic [21].

No published data exist on the influenza vaccination rate in SSc patients. However, influenza vaccination coverage seems to be low in patients with inflammatory diseases [22, 23]. We recently observed that only 28% of 137 patients with CTD or vasculitides receiving CSs and/or ISs and followed in our internal medicine department had received inactivated flu shots during the preceding year [24]. Thus, we decided to evaluate the rate of influenza vaccination and the factors influencing it in SSc patients.

Patients and methods

Study design and patients

We assessed the influenza vaccination status of 177 patients fulfilling the ACR [25] and/or LeRoy and Medsger [3] criteria for SSc. Patients were evaluated during annual meetings of the French association of SSc [Association des Scle´ rodermiques de France (ASF)] in March 2006 (n = 71) and March 2007 (n = 70) or during hospitalization between 2 April and 30 June 2007, in the Internal Medicine Department of Cochin Hospital (n = 36). Four physicians (L. M., C. M., A. B. and P. G.) working in our internal medicine department, a national referral centre for necrotizing vasculitides and SSc at Paris Descartes University, gave patients a one-page standardized questionnaire to complete, then interviewed patients for 15 min and checked for unanswered questions and completed questions, which included questions on clinical data for SSc.

Data collection

Information was collected on: sex; age; occupation; BMI; Karnofski index score; age at diagnosis; disease duration; disease form (SSc, lcSSc or dcSSc); year of onset of Raynaud’s syndrome; year of onset of the first non-RP; dyspnoea [assessed by the New York Heart Association (NYHA), 4-point scale]; pitting scars; digital ulcers; calcinosis; oesophagus, joint and/or muscle involvement; heart involvement and ILD; PAH; renal crisis; evidence of oesophageal, joint and/or muscle involvement of heart involvement and ILD; PAH; renal crisis; evidence of oesophagus, joint and/or muscle involvement; heart involvement, ILD, PAH and scleroderma renal crisis was based on patient self-reporting; and IS therapy (type and dose).

We recorded indication(s) for influenza vaccination (i.e. age ≥65 years, chronic disease—diabetes mellitus, heart, pulmonary or renal disease, haemoglobinopathy, cellular immune deficiency) and/or professional activity indicating vaccination. Patients self-reported vaccination during the previous year or earlier. Patients vaccinated during the previous year were asked whether vaccination had been ‘proposed by a general practitioner or specialist’; those who were not vaccinated were asked why. Possible answers included ‘not suggested by any physician’, ‘fear of side effects’, ‘concern of vaccine clinical effectiveness’ and ‘allergy’. In addition, patients were asked if they remembered receiving the letter from the French National Health Insurance Agency (FNHIA) sent annually to patients aged ≥65 years and/or with chronic disease to encourage them to get a free flu shot. Finally, patients were asked if they had been vaccinated against other infectious agents and when.

Quality-of-life assessment

The French version of the Medical Outcomes Study (MOS) 36-item short-form health survey was used to assess the quality of life [26, 27]. This self-administered questionnaire covers eight areas: physical function, physical role, bodily pain, general health, vitality, social function, emotional role and mental health. For each area, the score ranges from 0 (poor health status) to 100 (better health status). Scores can also be summarized in two global scores: the physical component score (PCS) and the mental component score (MCS). This scale has been validated in French [26].

Disability assessment

Global disability was assessed using the HAQ [28], the scale ranging from 0 (no disability) to 3 (maximal disability). The HAQ comprises 20 items divided into eight domains and has been validated in French [29].

Anxiety and depression assessment

Anxiety and depression were assessed by use of the Hospital Anxiety and Depression scale (HADa and HADd, respectively) [30]. This scale has seven questions for anxiety and seven for depression. Each question is scored from 0 to 3, and the total score ranges from 0 (no depression, no anxiety) to 21 (maximal depression, maximal anxiety).

Ethical considerations

This survey was conducted in compliance with the protocol Good Clinical Practices and Declaration of Helsinki principles. In accordance with French law, a formal approval from an ethics committee is not required for this kind of project. Patients gave their consent to participate after being orally informed about the study protocol.

Statistical analysis

Quantitative variables are described with means (s.d.) and ranges. Qualitative variables are described with proportions and percentages. To identify factors significantly associated with influenza vaccination, we used Fisher’s exact test to compare the distributions of categorical variables (sex, type of SSc, disease form and treatment, indication(s) for vaccination, FNHIA letter, previous history of influenza vaccination and year of last vaccination other than for influenza) for patients vaccinated or not during the preceding year. Student’s t-test was used to compare
age distributions in the two groups of patients. Variables showing significant association with influenza vaccination on univariate analysis were further included in a multiple logistic regression model. P ≤ 0.05 was considered statistically significant. Data analysis involved use of Systat 9 (SPSS, Chicago, IL, USA).

**Results**

**Characteristics of SSc patients included in the study**

The main characteristics of the 177 patients with SSc are reported in supplementary table 1, available as supplementary data at *Rheumatology* Online, whereas factors associated with receiving a flu shot are listed in Table 1. The mean (s.d.) age and disease duration at the time of evaluation was 58.7 (12.6) and 10.5 (9.5) years, respectively. Fifty-three patients (29.9%) had a professional activity. Seventy-nine (44.6%) patients had ILD and 20 (11.3%) had PAH. The mean (s.d.) of NYHA dyspnoea score was 2.09 (0.75). Forty-five (25.4%) patients received CSs and 42 (23.7%) ISs. A total of 139 (78.5%) patients had at least one other indication for influenza vaccination: 57 (32.2%) were ≥65 years, 38 (21.5%) had at least one chronic disease, 62 (35%) received ISs and/or CSs and 4 (2%) were health care workers. Only 38 (21.5%) patients had no indication other than SSc for vaccination.

**Influenza vaccination coverage**

Overall, 69 (39%) patients had received a flu shot during the preceding year: 50.7% were ≥65 years old, whereas only 20.4% of those who did not receive a flu shot were <65 years old (P = 0.0001). The percentages of vaccinated patients according to SSc disease form were 7% for ISSc, 65% for lcSSc and 28% for dcSSc. Fifty-four per cent of vaccinated patients had followed a general practitioner’s recommendation and 20% followed a specialist’s.

Among the 108 patients not vaccinated, 78 (72.2%) presented at least one indication for vaccination: age ≥65 years (n = 22); received CSs (n = 28) and/or ISs (n = 28); and/or ILD (n = 44) leading to chronic respiratory insufficiency (n = 6), PAH (n = 12), left-ventricular insufficiency (n = 6), cancer (n = 5), chronic renal insufficiency (n = 3) or diabetes mellitus (n = 1); or a professional activity indicating flu shot (n = 3). Of all 177 patients, 65 had remembered receiving the letter from the FNHIA: 57% of these were vaccinated and 26% were not (P = 0.0001).

Among the 108 patients not vaccinated, the most frequently cited reasons for non-vaccination were no doctor recommended it (n = 39, 36.1%), fear of side effects (n = 25, 23.1%) and fear of inefficacy (n = 4, 4%). Two patients declined because of allergy.

**Factors potentially associated with influenza vaccination in the preceding year**

Patients who had received a flu shot during the preceding year were significantly older at disease onset and at the time of evaluation than those who were not vaccinated [52.3 (13.7) vs 45.5 (11.7) years; P = 0.001 and 63.9 (12.1) vs 55.4 (11.8) years; P < 0.0001, respectively] (Table 1). Among the clinical parameters investigated, pitting scars were less frequently encountered in patients who had been vaccinated during the preceding year than in those who had not (47.8 vs 63.9%; P = 0.04), and dyspnoea was more frequently found in patients who had been vaccinated than in those who had not [2.23 (0.73) vs 1.97 (0.75); P = 0.03]. Patients who had and had not been vaccinated did not differ in any of the other clinical parameters investigated (Table 1). Patients with a professional activity had less frequently been vaccinated than those without a professional activity [10 (14.5%) vs 43 (39.8%); P < 0.0001] (Table 1). Patients who had and had not been vaccinated did not differ in receiving ISs or CSs. The number of patients receiving a given IS were too few for statistical analysis.

For year of the last vaccination other than for influenza, the interval was longer for patients who had not received a flu shot during the previous year than for those who had (P < 0.0001). For patients who had not been vaccinated, 43 (39.8%) had not received any vaccine during the last 5 years and 20 (18.5%) could not remember the date of the last vaccination.

The vaccination rate was significantly higher for patients who had received a previous flu shot than among those who had not (P = 0.0001), for those who had other indications for vaccination than for those who did not (P = 0.001) and for patients who remembered receiving the FNHIA letter than for those who did not remember (P = 0.0001). Patients who had and had not received a flu shot did not differ in global disability, anxiety, depression or quality of life (data not shown).

On multivariate analysis of age, pitting scars, dyspnoea score, professional activity, FNHIA letter, year of last vaccination, associated diseases indicating vaccination and year of the last other vaccination, year of the last flu shot and age at the time of evaluation were the two independent parameters significantly associated with influenza vaccination.

**Discussion**

We provide evidence that influenza vaccination coverage is low in patients with SSc. Only 39% of SSc patients had received a flu shot during the preceding year. Among the patients who did not receive flu shots, 78 (72.2%) presented with at least one indication for vaccination. These results, although low, are not surprising: in a recent study of 137 patients with CTD or vasculitides who received CSs and/or ISs and were followed in our Internal Medicine Department, only 28% had received inactivated flu shots during the preceding year [24].

The issue of vaccine-preventable diseases is a challenging question in immunocompromised patients, including those receiving ISs. Long-term immunosuppressive therapy [e.g. long-term use of CSs/AZA, cyclophosphamide (CYC) and mycophenolate mofetil] is sometimes used for severe SSc. Various therapeutic strategies have been proposed for SSc-associated ILD. Immunosuppressive agents were tested in the late 1980s, and 5-FU...
(fluorouracil) and chlorambucyl failed to demonstrate benefit in placebo-controlled trials. For >15 years, CYC has been used to treat SSc-associated ILD [19]. The results of two recent, prospective, randomized trials do not favour the use of CYC for SSc-associated ILD [31, 32], although limited benefit was observed in patients treated with oral CYC as compared with placebo in the scleroderma lung study [31]. In addition, open and/or retrospective studies of patients with early diffuse SSc revealed an improved Rodnan skin score on treatment with CYC [33, 34] and mycophenolate mofetil [35]. In the present study, 42 (23.7%) of the 177 SSc patients were receiving ISs. These therapies have their greatest impact on cell-mediated immunity, although T cell-dependent antibody production can also be adversely affected. There is no contraindication to any inactivated vaccine for patients receiving ISs for systemic inflammatory disease, and an annual flu shot is strongly recommended. Despite those recommendations, only 10 of 42 (23.8%) SSc patients receiving ISs received a flu shot in our study.

At the time of the recent identification of a novel swine-origin influenza A (H1N1) virus as the cause of an outbreak of febrile respiratory infection [36], it is important to recall that Influenza is a seasonal disease occurring in epidemics and new virus variants cause substantial morbidity and mortality in patients with high-risk

### TABLE 1

Univariate analysis of factors associated with influenza vaccination (‘flu shot’) in 177 patients with SSc

<table>
<thead>
<tr>
<th>Factor</th>
<th>Flu shot, n = 69</th>
<th>No flu shot, n = 108</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at disease onset, mean (s.d.), years</td>
<td>45.5 (11.7)</td>
<td>52.3 (13.7)</td>
<td>0.001</td>
</tr>
<tr>
<td>Age at the time of evaluation, mean (s.d.), years</td>
<td>63.9 (12.1)</td>
<td>55.4 (11.8)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Sex (women)</td>
<td>55 (79.7)</td>
<td>83 (73.8)</td>
<td>0.65</td>
</tr>
<tr>
<td>SSC disease duration, mean (s.d.), years</td>
<td>11.8 (9.6)</td>
<td>9.8 (8.3)</td>
<td>0.20</td>
</tr>
<tr>
<td>SSC disease form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limited</td>
<td>5 (7)</td>
<td>6 (5)</td>
<td></td>
</tr>
<tr>
<td>Limited cutaneous</td>
<td>45 (65)</td>
<td>68 (63)</td>
<td>0.71</td>
</tr>
<tr>
<td>Diffuse cutaneous</td>
<td>19 (28)</td>
<td>44 (41)</td>
<td>0.13</td>
</tr>
<tr>
<td>SSC cutaneous involvement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RP</td>
<td>67 (97.1)</td>
<td>104 (96.3)</td>
<td>0.77</td>
</tr>
<tr>
<td>Telangiectasias</td>
<td>54 (78.2)</td>
<td>95 (88)</td>
<td>0.12</td>
</tr>
<tr>
<td>Pitting scars</td>
<td>33 (47.8)</td>
<td>69 (63.9)</td>
<td>0.04</td>
</tr>
<tr>
<td>Digital ulcers</td>
<td>18 (26.1)</td>
<td>39 (36.12)</td>
<td>0.15</td>
</tr>
<tr>
<td>Calcinosis</td>
<td>20 (29)</td>
<td>45 (41.7)</td>
<td>0.09</td>
</tr>
<tr>
<td>SSC visceral involvement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal tract involvement</td>
<td>60 (86.9)</td>
<td>94 (87.0)</td>
<td>0.99</td>
</tr>
<tr>
<td>Arthralgias</td>
<td>48 (69.8)</td>
<td>79 (73.1)</td>
<td>0.54</td>
</tr>
<tr>
<td>Myalgias</td>
<td>48 (69.8)</td>
<td>71 (65.7)</td>
<td>0.65</td>
</tr>
<tr>
<td>ILD</td>
<td>33 (47.8)</td>
<td>46 (42.6)</td>
<td>0.52</td>
</tr>
<tr>
<td>PAH</td>
<td>8 (11.6)</td>
<td>12 (11.1)</td>
<td>0.89</td>
</tr>
<tr>
<td>NYHA</td>
<td>2.23 (0.73)</td>
<td>1.97 (0.75)</td>
<td>0.03</td>
</tr>
<tr>
<td>Renal crisis</td>
<td>6 (8.7)</td>
<td>9 (8.3)</td>
<td>0.93</td>
</tr>
<tr>
<td>Indication(s) for influenza vaccination</td>
<td>61 (88.4)</td>
<td>78 (72.2)</td>
<td>0.016</td>
</tr>
<tr>
<td>Age &gt; 65 years</td>
<td>35 (50.7)</td>
<td>22 (20.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Chronic disease indicating influenza vaccination</td>
<td>20 (29)</td>
<td>18 (16.7)</td>
<td>0.052</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1 (1.5)</td>
<td>1 (0.9)</td>
<td></td>
</tr>
<tr>
<td>Chronic respiratory disease</td>
<td>6 (8.8)</td>
<td>6 (5.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>Left-ventricular insufficiency</td>
<td>12 (17.6)</td>
<td>6 (5.5)</td>
<td>0.03</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>3 (4.4)</td>
<td>3 (2.7)</td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>3 (4.4)</td>
<td>5 (4.6)</td>
<td></td>
</tr>
<tr>
<td>Professional activity</td>
<td>10 [14.5%]</td>
<td>43 [39.8%]</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Professional activity indicating influenza vaccination</td>
<td>1 (1.5)</td>
<td>3 (2.7)</td>
<td></td>
</tr>
<tr>
<td>CS</td>
<td>17 (25)</td>
<td>28 (25.9)</td>
<td>0.88</td>
</tr>
<tr>
<td>IS</td>
<td>14 (20.3)</td>
<td>28 (25.9)</td>
<td>0.85</td>
</tr>
<tr>
<td>Previous influenza vaccination</td>
<td>60 (97)</td>
<td>67 (62)</td>
<td>0.004</td>
</tr>
<tr>
<td>Letter from health insurer</td>
<td>37 (59)</td>
<td>28 (25)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Year of last vaccination other than influenza vaccination</td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Last year</td>
<td>50 (73.5)</td>
<td>10 (9.2)</td>
<td></td>
</tr>
<tr>
<td>Between 2 and 3 years ago</td>
<td>0</td>
<td>15 (13.9)</td>
<td></td>
</tr>
<tr>
<td>Between 3 and 5 years ago</td>
<td>3 (4.4)</td>
<td>14 (13)</td>
<td></td>
</tr>
<tr>
<td>Between 5 and 10 years ago</td>
<td>4 (5.9)</td>
<td>25 (23.1)</td>
<td></td>
</tr>
<tr>
<td>More than 10 years ago</td>
<td>3 (4.4)</td>
<td>18 (16.6)</td>
<td></td>
</tr>
<tr>
<td>Do not know</td>
<td>2 (2.9)</td>
<td>20 (18.5)</td>
<td></td>
</tr>
</tbody>
</table>

Data are represented as n (%), unless otherwise indicated.
medical conditions. Flu shots have been shown to prevent all-cause deaths and hospitalizations during influenza epidemics among people with high-risk medical conditions [16]. Annual immunization before the start of the influenza season is strongly recommended for all adults with high-risk medical conditions [17, 18]. Moreover, prevention of influenza infection would help diminish the risk of bacterial lower-respiratory-tract infections, which may be particularly severe in SSC patients who frequently present with intraclinical lung involvement. Therefore, annual influenza vaccination could be of interest in many patients with SSC independently of IS treatment, because of the frequent development of severe visceral involvement, including PAH, ILD, left-ventricular dysfunction and/or renal insufficiency [10]. In our study, only 41.8% of the 79 SSC patients with ILD had received a flu shot during the previous year.

The most frequently cited reasons for non-vaccination were the absence of a doctor’s recommendation (36.1%) and fear of adverse effects (23.1%). The main issue concerning the vaccination of patients with inflammatory disease and/or drug-related immune deficiency is the possible reduction of vaccine efficacy and doubt about safety. Few published results exist of the efficacy and risks associated with vaccination of these patients [37]. Despite the availability of immunogenicity data, demonstrating the clinical efficacy of vaccines in this population is difficult. Thus, the current vaccination recommendations for these patients are based on correlates of protection established with immunocompetent subjects. The lack of data confirming the clinical efficacy of vaccination in this setting contributes to the low vaccine coverage among these patients [24]. For individuals with inflammatory diseases, the theoretical risk of relapse following vaccine administration represents an additional barrier to vaccination, and as a result, only a few recommendations exist to guide the decision to vaccinate these patients [38, 39]. No specific doubt surrounds the safety of vaccination for patients with SSC and no association of influenza infection or vaccination and SSC has been reported until now. A recent study of 46 SSC patients receiving a virosomal flu vaccine found no worsening of clinical conditions, inflammation or immunological parameters but humoral immune response in almost all patients, with protective titres in about 80% of them [21].

In our study, among the 177 SSC patients, only 69 (39%) had received flu shots during the past year: 50.7% of the patients were ≥65 years old vs only 20.4% who were <65 years old. Thus, the influenza vaccine coverage of patients ≥65 years was <70.1% in the general French population of the same age in 2005–06 [40]. The main reason for non-vaccination in our cohort was the absence of a doctor’s recommendation (36.1%). This rate is close to the 49% reported rate of non-vaccination in another study because ‘patients didn’t know they needed it’ [23]. The influenza vaccination coverage observed in our study could not be extrapolated to the general SSC population as the majority of patients involved in the study were ascertained from a patients’ meeting.

Thus, societies and colleges of physicians could recommend influenza vaccination for patients with SSC and thereby sensitize general practitioners and specialists to the issue. The lack of information and fear of secondary effects being the main factors explaining the lack of vaccination in our study, public health campaigns should be undertaken every autumn to improve the overall awareness of flu-shot recommendations for these patients. As well, the letter from the FNHIA about the free flu shot, sent to patients >65 years old and/or those with selected chronic health conditions, was significantly associated with an increased influenza vaccination rate. To improve influenza vaccination coverage in SSC patients, this letter should be mailed to SSC patients even if they do not meet any of the other standard criteria indicating vaccination. A prospective interventional study is required to assess if increasing awareness of flu-shot recommendations for SSC patients increases influenza vaccine coverage in these patients.

In conclusion, despite the common involvement of the lower respiratory tract occurring early in the course of SSC, influenza vaccination coverage is low in these patients. Lack of information and fear of secondary effects represent the main factors for not getting a flu shot. Efforts are needed to increase the influenza vaccination coverage in this population.

Rheumatology key messages

- Influenza vaccination coverage is low in SSC patients.
- The year of the last vaccination and age were two independent parameters associated with vaccination.
- Lack of information and fear of adverse effects are the most common reasons for non-vaccination.

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Supplementary data

Supplementary data are available at Rheumatology Online.

References

Influenza vaccination and SSc


