P5251

ALEFACEPT USE IN CLINICAL PRACTICE: THE A.W.A.R.E. PROGRAM

Robert Bissonnette, MD[1]; Ian DR Landells, MD[2]; Gordon E Searles, MD[3]; Neil H Shear[4]

[1]Innovaderm Research, Montreal, Quebec, Canada; [2]Nexus Clinical Research, St John's, Newfoundland and Labrador, Canada; [3]University of Alberta, Edmonton, Alberta, Canada; [4]University of Toronto, Toronto, Ontario, Canada

INTRODUCTION

- Psoriasis is estimated to affect 1 million people in Canada.[1]
- Psoriasis is treated with a variety of treatment options, either alone or in combination.
- Moderate to severe psoriasis is often treated with systemic therapy and/or combination therapy.
  - Conventional systemic therapies are effective but their safety profile may limit treatment options in many patients.
  - The introduction of biologic drugs has created an important advancement in the treatment of psoriasis.[2]
- Alefacept was the first biologic approved by Health Canada for the treatment of moderate to severe psoriasis.
  - A fully human fusion protein that inhibits T-cell activation and proliferation and induces apoptosis of memory effector T cells[3]
  - Efficacy and safety of alefacept at a weekly dose of 15 mg intramuscularly (IM) for 12 weeks have been established in clinical trials.[4]
  - One of the unique attributes of alefacept is the ability to induce remission after 1 or 2 courses (a 50% reduction in Psoriasis Area and Severity Index (PASI) has been maintained for a median of 7 months).[5]
- Alefacept is used as monotherapy or as part of combination therapy.[6]
- A.W.A.R.E. (Amevive Wisdom Acquired from Real world Evidence) is an ongoing multicenter, phase 4 clinical study in Canada in patients with psoriasis treated with alefacept.
- Generation of a real-time database has several advantages, including networking among sites, development of a "best practices" model, and the optimization of the use of alefacept for Canadian patients with moderate to severe psoriasis.
- This is the first report of this ongoing study, in which we present the baseline patient demographic data.

OBJECTIVES

Primary

- To develop a shared, real-time national clinical database to support best practice and optimize the care of patients receiving alefacept

Secondary

- To generate hypotheses for future clinical research
- To gain understanding of how alefacept is used in routine clinical practice in real-world settings in Canada

METHODS

Study Design

- A multicenter, observational, prospective Canadian national trial
- Target enrollment: up to 600 patients with psoriasis in dermatology clinics across Canada (both community- and university-affiliated)
- Ethics approval has been obtained for all participating sites.

Inclusion Criteria

- Patients with psoriasis:
  - who are clinically indicated to receive alefacept and for whom the decision to be treated with alefacept has been made
  - who give informed consent
  - who agree to at least 52 weeks of follow-up

Follow-Up

- Patients are treated according to routine clinical care as provided by their physician, and are prospectively followed for at least 12 months depending upon when patients present for retreatment following an initial 12-week alefacept course.

Collection of Data

- At baseline, data are collected on:
  - patient demographics and relevant medical history
  - psoriasis history and treatment history
  - initial alefacept treatment plan and strategy
- At every follow-up visit, data are collected on:
  - treatment regimen
    - alefacept dosing
    - concomitant psoriasis therapies
  - efficacy
    - body surface area (BSA) involvement with psoriasis
    - Physician Global Assessment score
    - Patient Global Assessment score
    - time to retreatment with alefacept
  - safety
    - occurrence of serious adverse events
    - withdrawals

Management of Data

- Data from all participating sites are captured using a Web-based electronic data reporting system.
  - Sites have the ability to view preprogrammed reports online (even while the study is in progress) for their center and for aggregate sites.

INTERIM RESULTS

- Baseline characteristics of 362 patients across 36 participating clinics enrolled in the A.W.A.R.E. study (from May 2005 to July 20, 2007) are presented herein.

Patient Demographics

Table 1. Patient demographics (n=362)

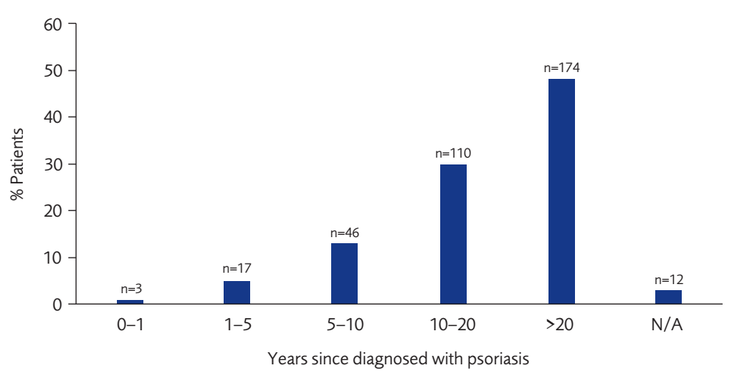
Age, y	
Mean ± SEM	46.7±0.6
Range	18–79
Age distribution, y, n (%)	
16–30	31 (9)
31–40	75 (21)
41–50	123 (34)
51–65	121 (33)
≥66	12 (3)
Gender, n (%)	
Female	193 (53)
Male	169 (47)
Region, n (%)	
Quebec/Atlantic	103 (28)
Ontario	158 (44)
Western	101 (28)

SEM=standard error of the mean.

Disease Characteristics at Baseline

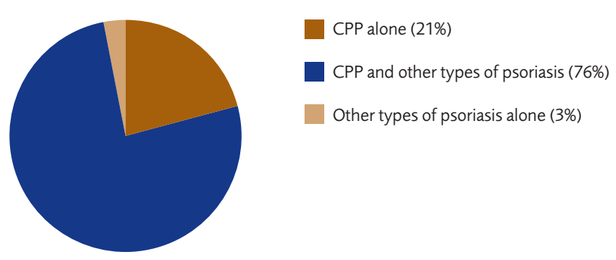
- A preponderance of patients (78%) had a longer than 10-year history of psoriasis (Figure 1).

Figure 1. History of psoriasis (n=362)



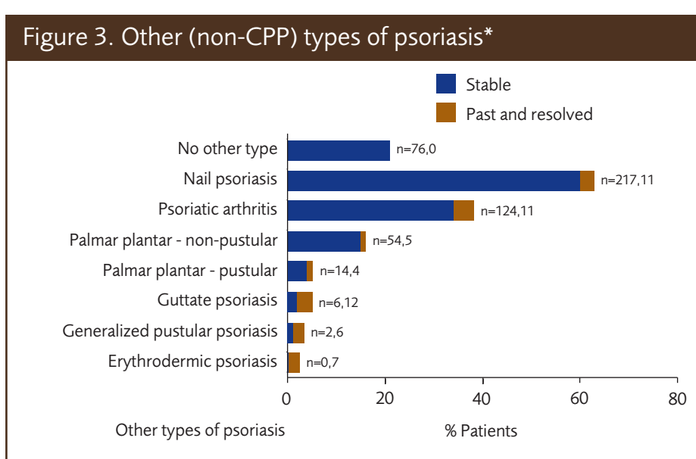
- 97% (351 of 362) of patients had chronic plaque psoriasis (CPP) (Figure 2).
  - 21% (76 of 362) of patients had only CPP.

Figure 2. Presence of CPP



- Other types of psoriasis reported in the A.W.A.R.E. population include nail psoriasis (60%) and psoriatic arthritis (34%) (Figure 3).

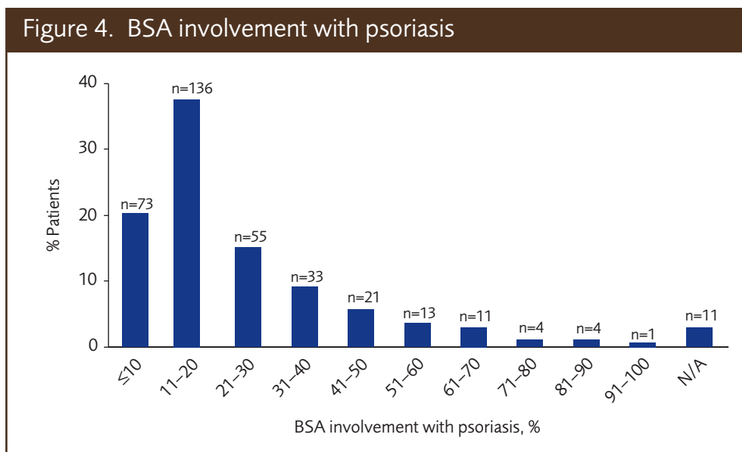
Figure 3. Other (non-CPP) types of psoriasis*



*Patients may have more than 1 type of psoriasis. Column percentages may total >100%.

- A majority of patients (77%) had greater than 10% BSA involvement with psoriasis (Figure 4).

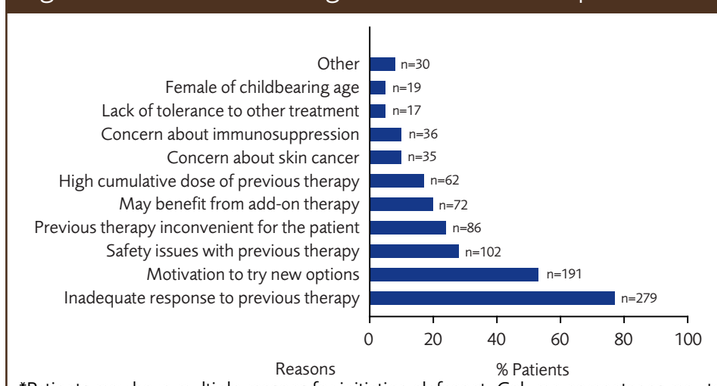
Figure 4. BSA involvement with psoriasis



Reasons for Initiating Treatment With Alefacept

- A majority of patients (77%) initiated treatment with alefacept because their previous therapy was inadequate (Figure 5).

Figure 5. Reasons for initiating treatment with alefacept*

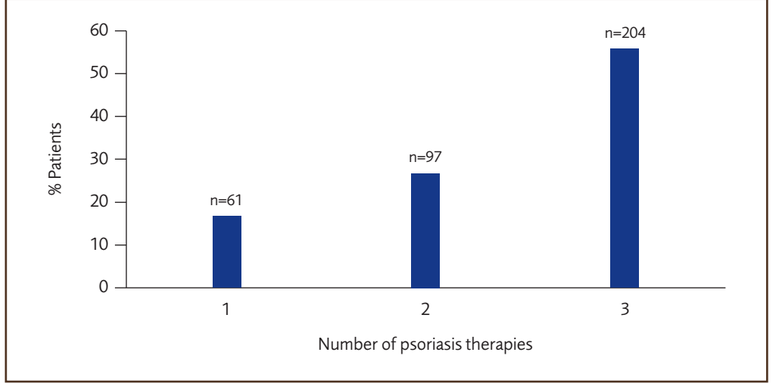


*Patients may have multiple reasons for initiating alefacept. Column percentages may total >100%.

Psoriasis Therapies Prior to and at the Time of Enrollment

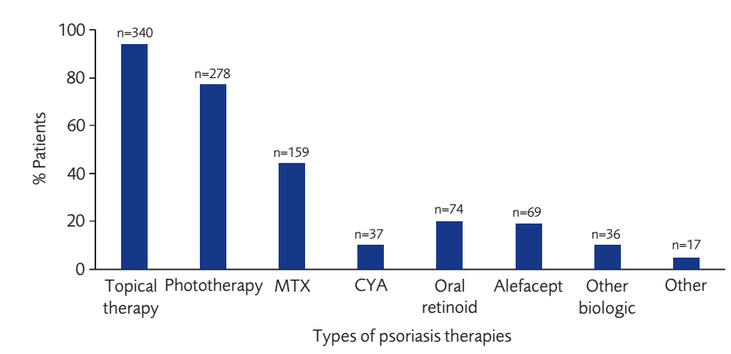
- Prior to enrollment and at the time of enrollment into the A.W.A.R.E. study, all patients were receiving 1 or more treatments for psoriasis; most patients (56%) were on 3 therapies (Figure 6A).

Figure 6A. Number of psoriasis therapies received prior to and at the time of enrollment (n=362)



- Topical therapies were most common (94%), followed by phototherapy (77%) and methotrexate (44%), as shown in Figure 6B.

Figure 6B. Types of psoriasis therapies received prior to and at the time of enrollment*

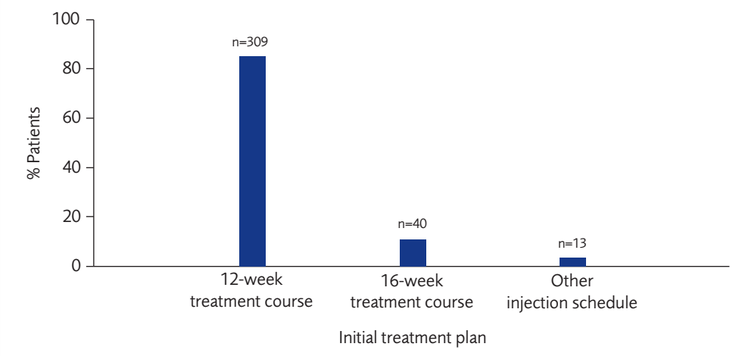


*Patients may be receiving multiple therapies. Column percentages may total >100%.
CYA=cyclosporine A; MTX=methotrexate.

Initial Alefacept Treatment Plan and Strategy

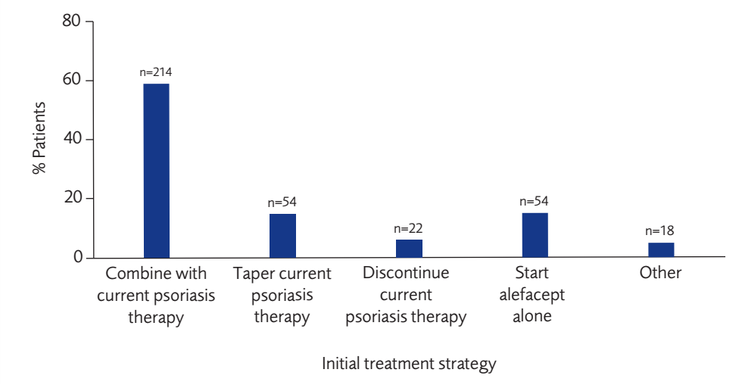
- The majority of the patients (85%) received the standard 12-week treatment course of alefacept (15 mg IM once-weekly injections) (Figure 7).

Figure 7. Initial alefacept treatment plan (n=362)



- For the majority of the patients (59%), alefacept was added to the current psoriasis treatment regimen (Figure 8).

Figure 8. Initial treatment strategy with alefacept (n=362)



CONCLUSIONS

- Key findings from the baseline characteristics of patients with psoriasis enrolled in the A.W.A.R.E. study:
  - Treatment with alefacept was most frequently initiated in subjects with greater than 10% BSA involvement.
  - Lack of adequate response to previous psoriasis therapy was the leading cause of initiating treatment with alefacept.
  - The initial treatment strategy for most patients involved adding alefacept to their current regimen.
- The A.W.A.R.E. study offers an opportunity to study the use of alefacept in clinical practice and will bring new insights to future research initiatives.

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