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BACKGROUND

Acitretin is an oral synthetic aromatic analogue of retinoic acid available in most European countries since 1988 used mainly for treatment of severe forms of psoriasis. Like all systemic retinoids, acitretin is teratogenic. Due to transesterification of acitretin to etretinate in presence of ethanol, pregnancy should be avoided for at least 2 years after treatment discontinuation. Strict pregnancy prevention in female acitretin users of child-bearing age is required.

OBJECTIVES

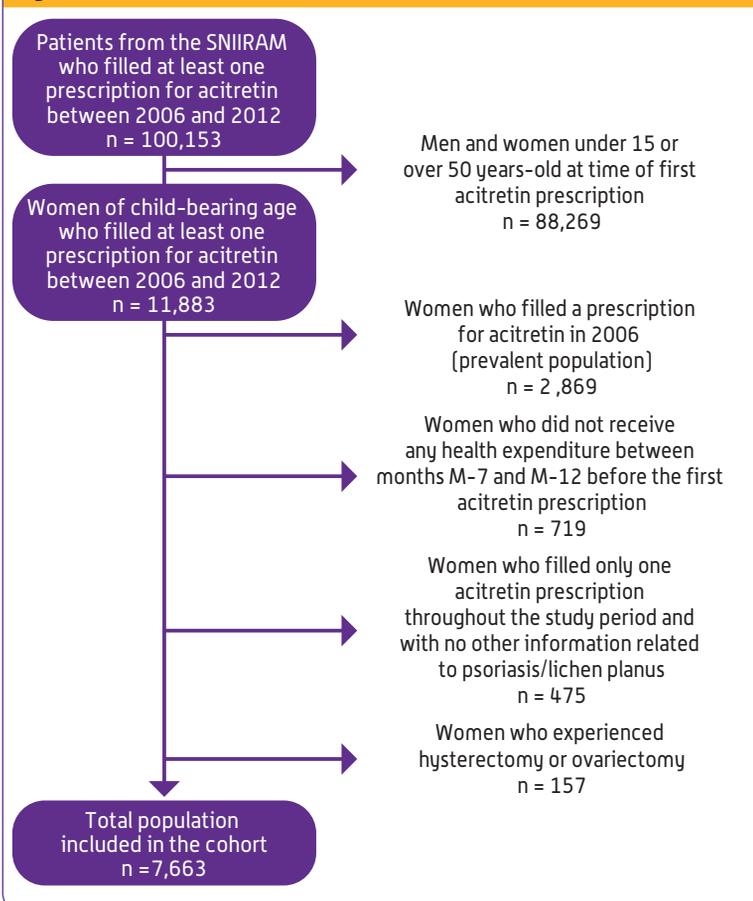
To assess compliance with pregnancy prevention recommendations, specifically looking at pregnancy testing compliance and pregnancy occurrence.

METHODS

1. Patients selection

A cohort of women aged 15-49 years initiating an acitretin treatment from January 2007 to December 2012 was identified using French SNIIRAM (reimbursement data) and PMSI (hospitalisations data) databases.

Figure 1: Flow chart



2. Outcomes

a) Pregnancy tests (PTs) were identified from reimbursed urine or serum (B) HCG laboratory PTs. In order to fulfil pregnancy testing criteria, patients who started treatment needed to have a PT performed 3 or fewer days before they bought acitretin.

b) Pregnancies were identified based on hospital stay related to a pregnancy or outpatient's medicinal abortion. The pregnancies screened for their teratogenic risk were those confirmed during acitretin treatment or which began within two years after the last acitretin filling.

RESULTS

Table 1: Patients' characteristics

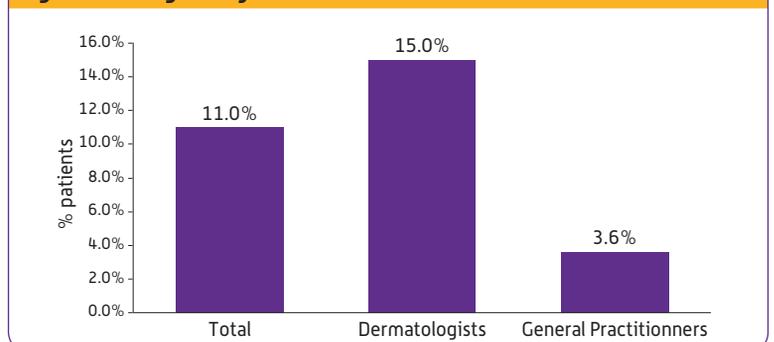
	Study population
Mean age, y (sd)	39.5 (8.3)
Total number of acitretin courses ¹	8,121
Mean number of acitretin courses per patient	1.06
Number of acitretin prescription [%]	
1	2,591 (33.8)
2	1,171 (15.3)
3 to 11	2,980 (38.9)
> 12	921 (12.0)
At least one other treatment related to psoriasis during study period [%] ²	6,066 (79.2)
Including:	
Topical psoriasis treatment	5,921 (77.3)
Phototherapy/Puvotherapy	1,621 (21.2)
Ciclosporin or Methotrexate	1,100 (14.3)
Anti-TNF alpha	325 (4.2)
Topical corticosteroids [%] ³	6,136 (80.1)
Hospitalisation with a diagnosis of psoriasis [%]	723 (9.4)
LTD psoriasis/Lichen planus [%]	442 (5.8)

Sd, standard deviation ; LTD, Long Term disease ; ¹ a group of acitretin prescriptions for which the time between 2 prescriptions is less than 12 months ; ² during study period (2006-2012) ; ³ within the 12 months before or after acitretin initiation.

a) Pregnancy tests rate

- At initiation, a PT was carried out in 11% of women.
- During treatment, a PT was carried out every 2 months in 10% of women.
- After treatment discontinuation (2-year period), only 1 patient had a PT performed every 2 months.

Figure 2: Pregnancy tests rate before acitretin initiation



b) Pregnancy occurrence

Table 2: Pregnancy outcomes according to years of delivery

	Birth ¹ n=218	Elective or spontaneous abortion n=129	Extra-uterine pregnancy n=10	Total n=357
Mean age, y (sd)	31.2 (5.2)	33.0 (6.2)	32.4 (5.6)	31.9 (5.7)
Years of delivery				
2007	2	5	1	8
2008	19	15	0	34
2009	31	30	4	65
2010	35	20	1	56
2011	70	36	2	108
2012	61	23	2	86

¹ including one still-birth

CONCLUSION

This study showed the non-compliance of pregnancy prevention recommendations of acitretin treatment in France. Physicians, pharmacists and patients should be better informed about these recommendations.