

Hydrosorb® versus control (water based spray) in the management of radio-induced skin toxicity: Results of multicentre controlled randomized trial



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Purpose

To report the results of a randomised study comparing the efficacy of Hydrosorb® versus control (water based spray) in the topical treatment of grade 1 and 2 radiation dermatitis in population of patients treated for early stage breast cancer.

Hydrosorb® - Technical features

Hydrosorb® is a transparent, solid hydrogel sheet with a semi-permeable outer layer.



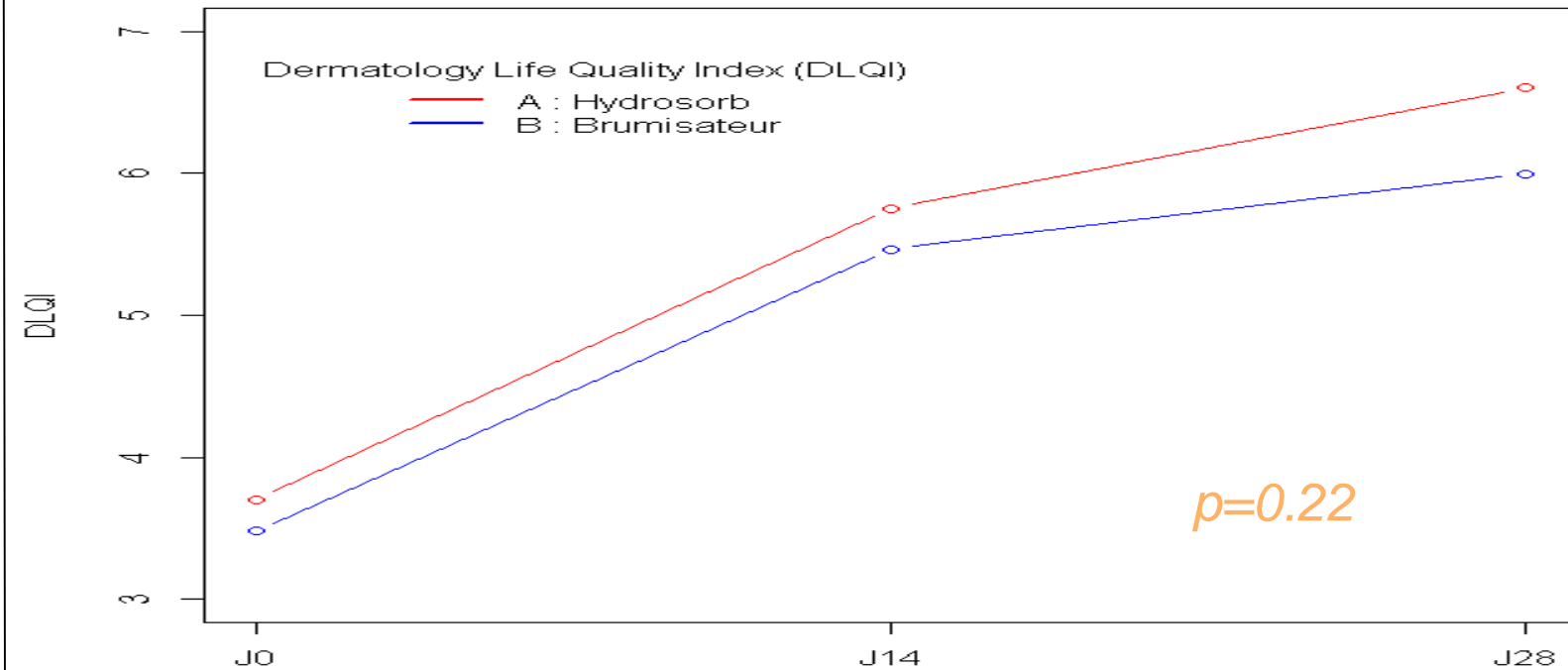
Primary objective

Avoiding deterioration and/or restoring the integrity of the skin

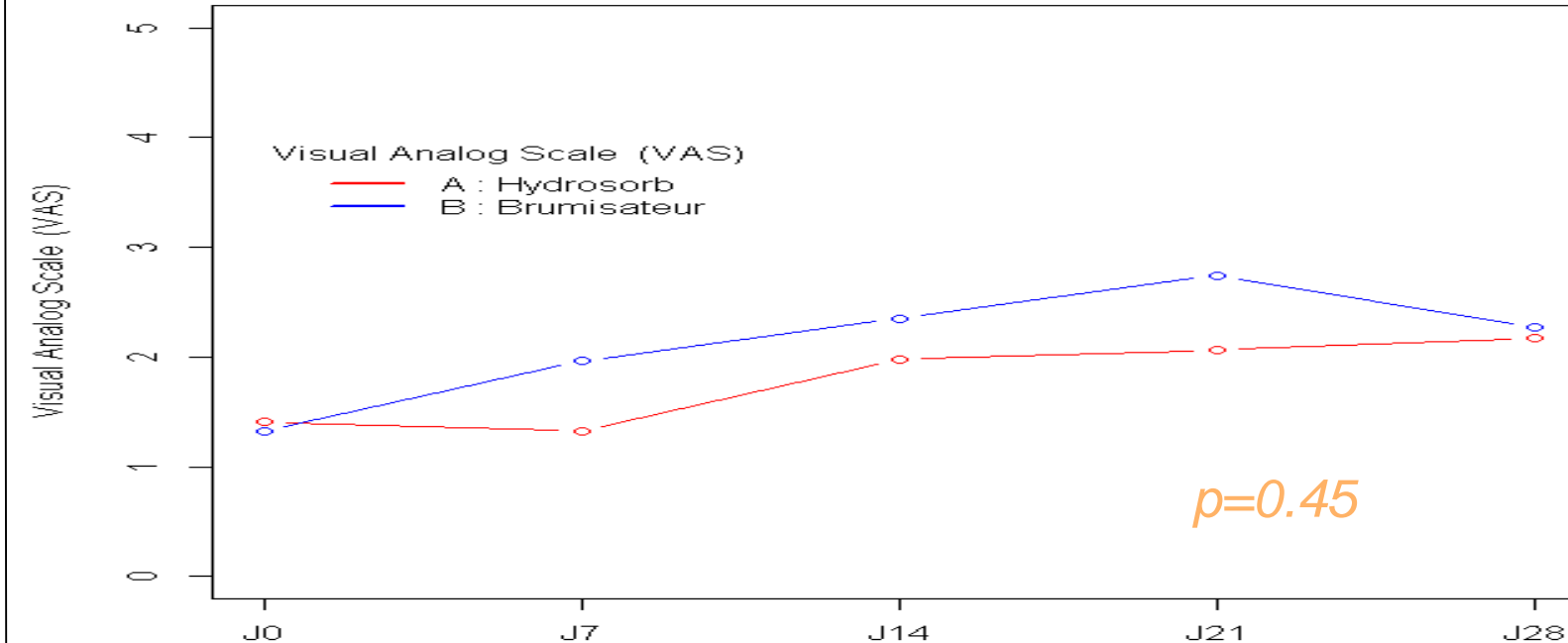
	HYDROSORB®	placebo	p
Success (%)	82 (57,7)	74 (54,6)	0,58

Secondary objective

❖ Dermatology Life Quality Index (DLQI)

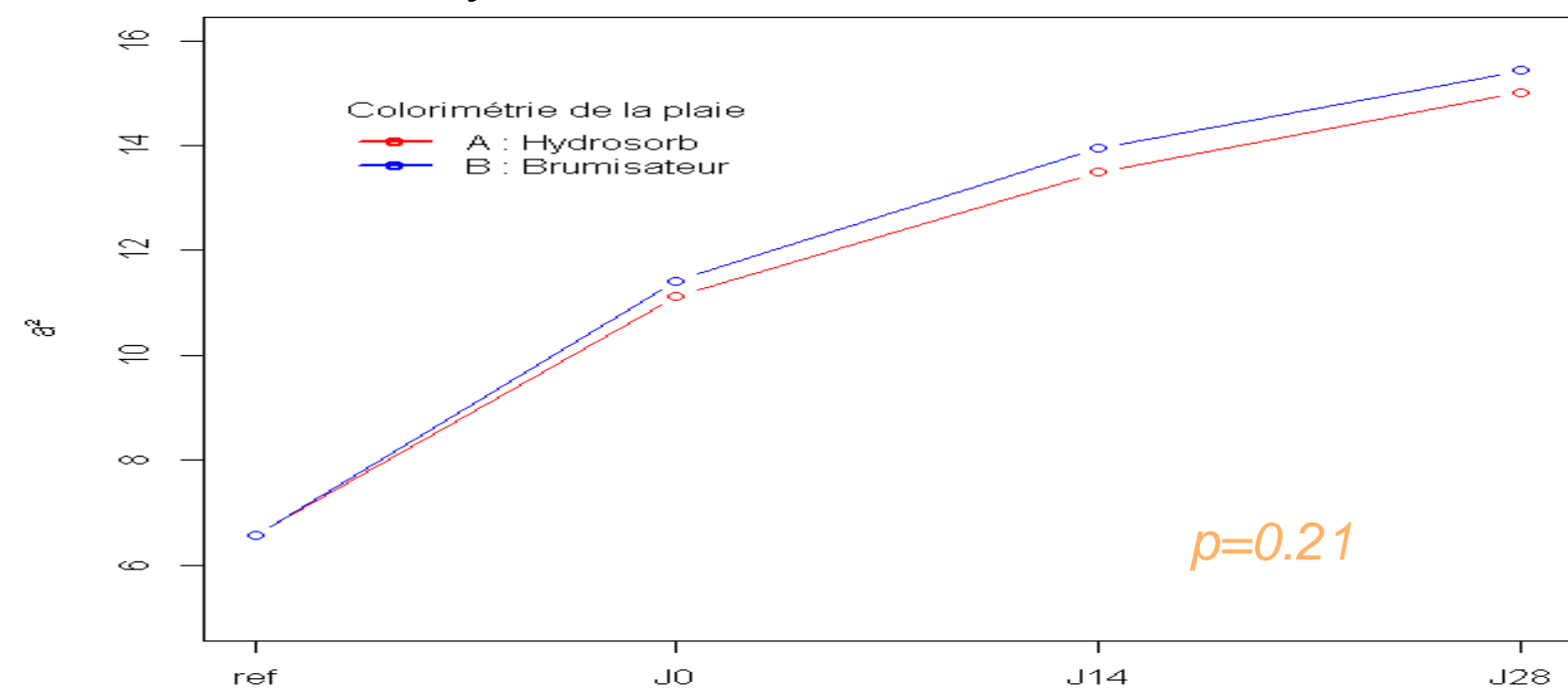


❖ Visual Analog Scale (VAS)



VAS >2 n(%)	HYDROSORB®	Placebo	p
J0	28(19.7)	27(19.9)	0.98
J7	27(19)	47(34.6)	0.004
J14	41(28.9)	53(39.0)	0.08
J21	42(29.5)	61(44.9)	0.01
J28	48(33.8)	51(37.5)	0.45

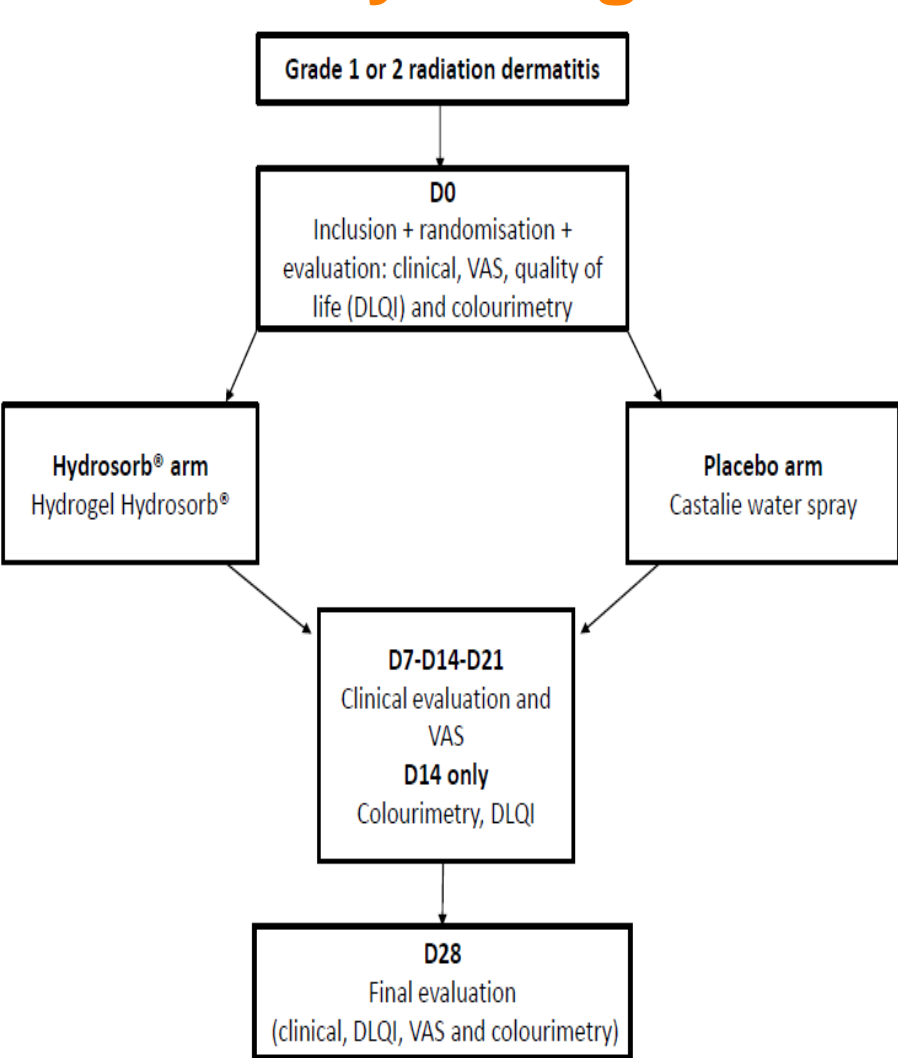
❖ Colourimetry



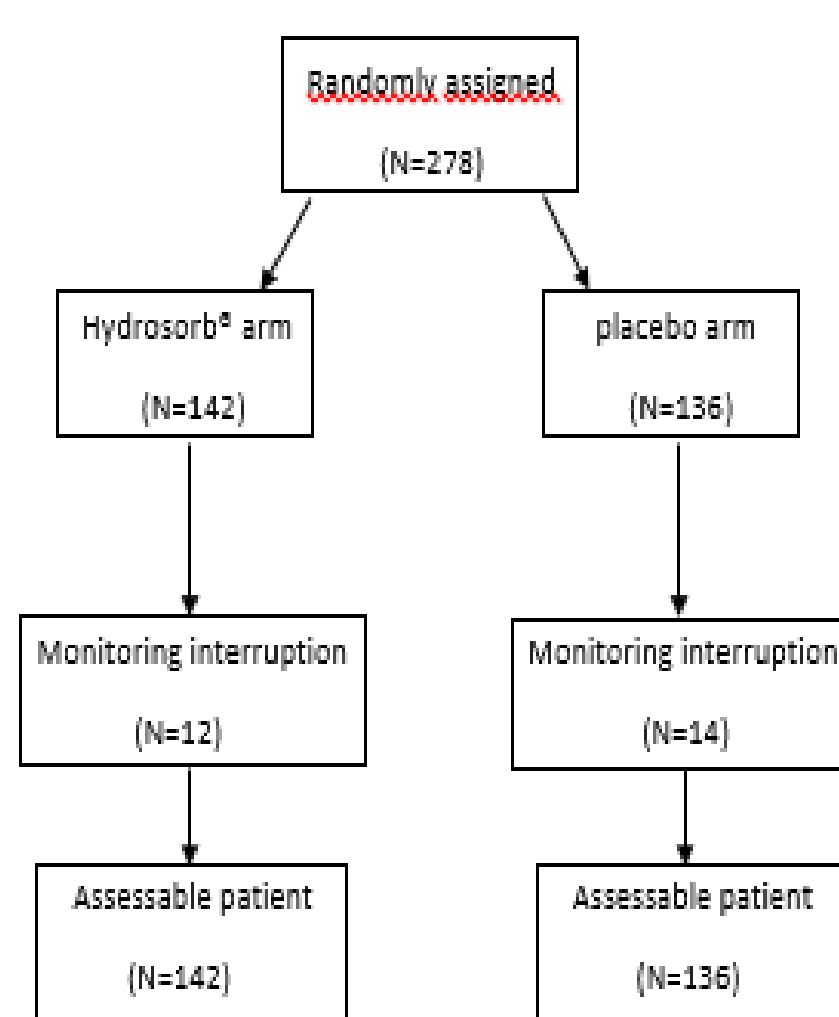
CONCLUSION

This study showed no significant difference between Hydrosorb® and simple water spray in the treatment of acute radiodermatitis even if there was slight pain improvement at the first weeks.

Study design



Flow-chart



Patients' characteristics

	HYDROSORB®	%	Placebo	%	p
Nombre patientes	142		136		
Age médian (min-max)	53 (33-84)		53 (21-86)		0.45
IMC* médian (min-max)	23.8 (17.5-40.1)		24.2 (17.1-41.5)		0.33
Tabac					0.90
Oui	21	14,8	21	15,4	
Diabète					0.46
Oui	3	2,1	6	4,4	
Chimiothérapie première					0,73
Oui	66	46,5	66	48,5	
Epithélie					1,0
1	140	98,6	135	99,3	
2	2	1,4	1	0,7	
Dose reçue médiane (min-max) J0 (Gy)	26 (8-50)		26 (10-56)		0.64
Colorimétrie médiane (min-max)	11.2 (6.5-19.3)		10.9 (1-20)		0.33
Coloration en 2 catégories (%)					0.22
Saine ou (+)	131	92,2	121	89,0	
+, ++, +++	8	5,6	13	9,6	
Surface médiane (cm²)	3.57		3,36		0,94
Douleur EVA					0,98
>2	28	19,7	27	19,9	
Hormonothérapie					0,91
Oui (%)	12	8,5	11	8,1	