



BENEFIT-RISK ANALYSIS IN ABSENCE OF CLINICAL EVIDENCE

DECIDING FOR TREATMENT OF SKULL DEFORMATION IN BABIES AGED 5 MONTHS

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Skull deformation (SD) is a flattening of the head as a result of pressure on the malleable skull in infants in the first months of life. Skull shape will normalize to a certain extent as a result of natural processes. In recent years, a helmet or headband was promoted to speed up and/or increase recovery. The evidence for the additional effect of the helmet is of low quality. Burden of helmet treatment is considerable; the helmet has to be worn 23 hours a day for at least 6 months.



OBJECTIVES: With the lack of high quality evidence in favor of the helmet, the main question is whether the expected effect of the helmet is worth the burden of treatment. The objective of this study is to estimate the risk-benefit trade-off in SD management in pediatric physiotherapists.

METHODS: A total of 267 pediatric physiotherapists stated their preference for treatment of a 5 month old child with SD through discrete choice experiments (DCE). Logistical regression and Hierarchical Bayes analysis was performed to analyze the results.

Attribute	Level	Partworth utility	[95% Conf. Interval]	
management	natural recovery	0,7440	0,8759	0,6120
	helmet	-0,7440		
time till effect	1 year	0,8411	0,9590	0,7232
	3 years	-0,8411		
effect size	9/10 success rate	1,5456	1,6958	1,3953
	6/10 success rate	-0,0888	0,0373	-0,2149
	5/10 success rate	-1,4568		
pressure sores	no pressure sores	0,5026	0,6304	0,3749
	pressure sores	-0,5026		
skin reaction	no skin rash	1,0713	1,2038	0,9388
	skin rash	-1,0713		
acceptation	no acceptation issues	1,0488	1,1810	0,9166
	acceptation issues	-1,0488		

RESULTS: Pediatric physiotherapists' preferred treatment that has a high probability of timely success without harms. At present, most attributes indicate a strong preference for awaiting natural recovery. Risk benefit assessment favoring the helmet will only be attained if the helmet can show highly significant clinical benefit.

CONCLUSIONS: This study shows that risk benefit analysis can give early indications on the potential of a new treatment. In this study, the threshold at which treatment is more preferred to natural recovery is determined. Results indicate that at present, the available evidence does not support active intervention in SD.

