

Cleft Lip and Palate: An Objective Measure Outcome Study

Hani Sinno, M.D.
 Youssef Tahiri, M.D.
 Stephanie Thibaudeau, M.D.
 Ali Izadpanah, M.D.
 George Christodoulou, B.Sc.
 Samuel J. Lin, M.D.
 Mirko Gilardino, M.D.

Montreal, Quebec, Canada; and
 Boston, Mass.

Background: Cleft lip and/or palate is a debilitating condition if left unrepaired, resulting in significant speech, hearing, swallowing, feeding, and psychosocial impairments. The authors' objective was to determine the potential impact of being born with cleft lip and/or palate by using previously validated health state utility assessment measures.

Methods: A utility assessment using the visual analogue scale, time trade-off, and standard gamble was used to obtain utilities for cleft lip and/or palate, monocular blindness, and binocular blindness from a prospective sample of the general population and medical students. Average utility scores were compared using paired *t* test. Linear regression was performed using age, race, and education as independent predictors of each of the utility scores.

Results: Over a 1-year prospective enrollment period, 110 participants were included in our utility analysis. The utility outcome scores for cleft lip and/or palate (visual analogue scale, time trade-off, and standard gamble, 0.69 ± 0.18 , 0.85 ± 0.16 , and 0.84 ± 0.18 , respectively) were statistically different from those of binocular blindness (visual analogue scale, time trade-off, and standard gamble: 0.38 ± 0.17 , 0.70 ± 0.24 , and 0.66 ± 0.25 , respectively; $p < 0.001$) but not statistically different from those of monocular blindness (visual analogue scale, time trade-off, and standard gamble, 0.67 ± 0.15 , 0.86 ± 0.15 , and 0.84 ± 0.18 , respectively). There was no statistically significant difference in utility scores between male and female participants.

Conclusion: The results of the study demonstrate objectively via health state utility scores that the perceived burden of being born with cleft lip and/or palate is comparable to living with monocular blindness. (*Plast. Reconstr. Surg.* 130: 408, 2012.)

Cleft lip and/or palate is the most common congenital anomaly of the craniofacial region.¹⁻⁴ In addition to the aesthetic disfigurement, a child with cleft lip and/or palate can suffer significant functional morbidity, including restricted maxillofacial growth, speech anomalies, swallowing and feeding difficulties, hearing loss, and/or recurrent ear infections.^{5,6} Although not generally life-threatening, living with and being treated for cleft lip and/or palate elicits an obvious burden on the patient and family.

To objectify the burden of a particular health state, different tests have been designed.⁷⁻¹¹ These tools include the standard gamble,¹² time trade-off,¹³ and visual analogue scale.¹⁴ As recommended by an expert panel on cost effectiveness in health and medicine, these health states utility scores can be measured from a sample of the general population based on a case presentation,⁹⁻¹¹ using an Internet-based Web site to recruit this random population sample.¹⁰

In the present study, the authors' aim was to measure the health state of a diagnosis of cleft lip and/or palate by using utility scores in an effort to objectify the relative burden of the cleft compared with other recognized debilitating diseases (such as blindness). With the continued streamlining of health care funding and insurability, such objec-

From the Division of Plastic and Reconstructive Surgery, Montreal Children's Hospital, McGill University; the Faculty of Medicine, McGill University; and the Division of Plastic and Reconstructive Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School.

Received for publication September 5, 2011; accepted February 14, 2012.

The first two authors contributed equally to the article.

Copyright ©2012 by the American Society of Plastic Surgeons

DOI: 10.1097/PRS.0b013e3182589d4b

Disclosure: *The authors have no financial interest to declare in relation to the content of this article.*