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ORAL REHABILITATION WITH COMPLETE IMPLANT-SUPPORTED DENTAL PROSTHESIS: A BUDGET IMPACT ANALYSIS FROM THE UNIFIED HEALTH SYSTEM PERSPECTIVE

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ABSTRACT

Objective: The aim of the study was to estimate the budget impact of complete implant-supported dental prostheses in the rehabilitation of mandibular edentulism in patients within the context of the Brazilian national health system - "Sistema Único de Saúde" - SUS. **Methods:** Treatment with complete implant-supported dentures was compared with the technology most frequently used - Conventional Complete Dental Prosthesis. For analysis, we adopted the Methodology proposed by the Methodological Guidelines for Budget Impact Analysis of the Brazilian Network for Health Technology Assessment (REBRATS). Sensitivity analysis was performed per scenarios and a temporal horizon of 5 years was used. **Results:** Implementation of treatment by complete implant-supported dental prostheses would demand an amount of US$ 970,253,019.00 in 5 years in the reference scenario, US$ 545,767,323.40 in the most optimistic scenario, and US$ 1,516,020,342.40 in the worst scenario [US dollars, Year 2019]. **Conclusions:** These results could support the Brazilian managers in planning the Federal budget destined to Medium to High Complexity (treatments), making it possible to disseminate rehabilitative treatment performed with complete implant-supported dentures in SUS, and serve as reference for health systems in other countries.

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INTRODUCTION

In 2004, the Federal Government of Brazil launched the national oral health policy "Política Nacional de Saúde Bucal" – (PNSB) (Brasil, 2004a), which contemplated expansion of the offer of specialized dental assistance services. In spite of this advancement, the National Health Survey conducted in 2013 showed evidence that the accumulation of oral diseases over the course of years without support for treatment resulted in a high demand for oral prosthetic rehabilitation in the population (IBGE, 2013). Sixteen million Brazilians do not even have one single tooth in the mouth. Mandibular edentulism affects an even higher number of people, and is prevalent in 31.23% of the adults, and in 67.29% of elderly people as from the age of 60 years. In view of the high prevalence of the edentulism in Brazil, in 2004, the Ministry of Health (MH) started financing Conventional Complete Dental Prostheses (CCP), and in 2010 Complete implant-supported prostheses (CISP), for oral rehabilitation of edentulous patients (Brasil, 2004b; Brasil, 2010). Among these, the CISP is recognized as the type that offers patients a better fit in cases of edentulous mandibles (Das *et al*., 2012; Feine *et al*., 2002; Thomason *et al*., 2009). Considering that financial resources are limited, it is important for them to be use efficiently to provide a basis for the decision-making process of public policies. In this context, economic evaluation studies may help

to guarantee efficiency, especially by prioritizing attendance of patients requiring dentures among the demands on the available resources (Tan *et al*., 2017). Among the economic analyses in health, the purpose of the Budget Impact Analysis (BIA) is to identify which would be the financial consequences arising from the incorporation of a certain technology into a health system with a certain budget, by revealing the feasibility of this incorporation for users of the system. The BIA constitutes a fundamental tool for public health budget managers, to help with budget prediction in a defined time interval (Brasil, 2012). Although PNSB has made advances since its creation up to the time of its operationalization, the present scenario point out persistent challenges that are strongly bound to questions of financing. In this context, the aim of this study was to evaluate the budget impact pf the use of complete implant-supported dental prostheses (CISP) in comparison with treatment with conventional complete dental prostheses (CCP) in rehabilitative treatment of mandibular edentulism, within the context of the Brazilian national health system - SUS.

MATERIALS AND METHODS

Study Design: We designed a Budget Impact Analysis in accordance with the Methodological Guidelines of the Methodological Guidelines for Budget Impact Analysis of the Brazilian Network for Health Technology Assessment (REBRATS) (Brasil, 2012) and with the presupposition of gradual diffusion of oral rehabilitation by means of CISP on two implants. The presupposition of gradual diffusion was determined, because although there is an expectation that more effective technologies will be rapidly incorporated into clinical practice, this limitation must be recognized, particularly within the context of SUS. Diverse variables could interfere in the process of diffusion of a technology, such as for example, training and qualification of human resources, in addition to the culture itself of the patients (Brasil, 2012).

Technologies: The CISP on two implants has been pointed out as being the minimum treatment indicated for the rehabilitation of patients with edentulous mandibles (Das *et al*., 2012; Feine *et al*., 2002; Thomason *et al*., 2009). Nevertheless, the CCP is the treatment most frequently offered as the proposal for rehabilitation in SUS, and continues to be routinely used in dental clinical practice because of its low cost (Xie *et al*., 2015).

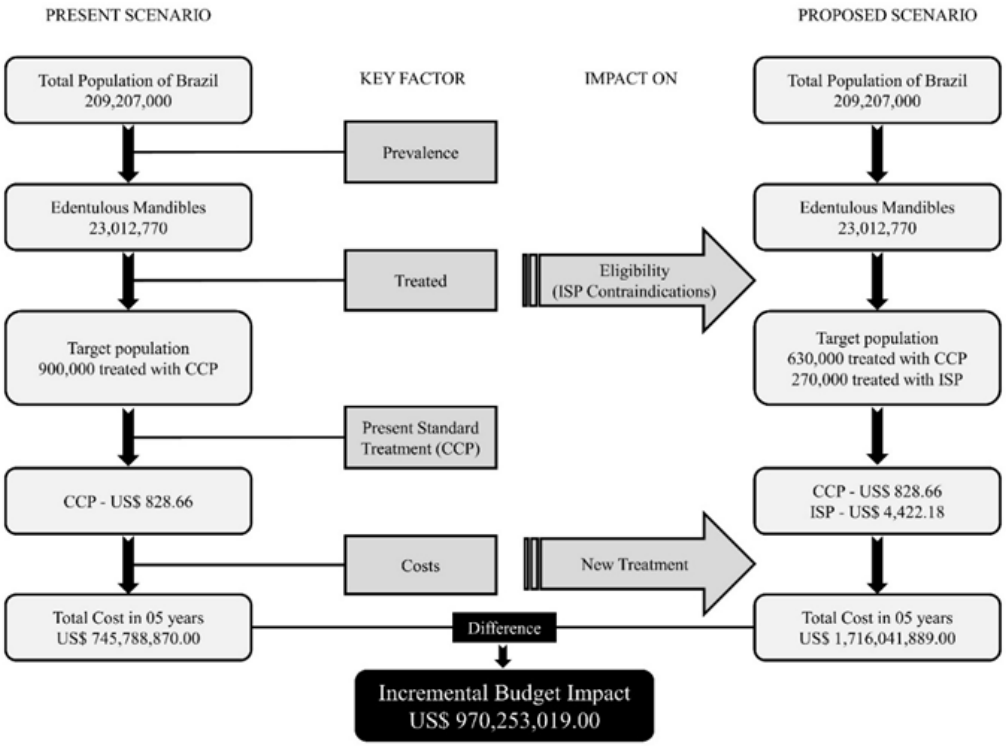
Perspective and Costs: We adopted the perspective of the Federal Management of the Brazilian National Health System - SUS (Ministry of Health of Brazil).We also applied no discount rate and adopted the horizon of 5 years, starting in 2020 through to 2024, as recommended in the Guidelines of REBRATS (Brasil, 2012). Federal government financing incentive was assumed for the incorporation of substitutive rehabilitation by means of implant-supported dental prostheses, from the perspective of the Federal manager. The method for collecting cost data was based on the top-down, or macro costing approach, and was obtained from the table of SIGTAP - system for management of the table of procedures, medications and OPM of SUS "Sistema de Gerenciamento da Tabela de Procedimentos, Medicamentos e OPM do SUS" (Brasil, 2017a).

Population of Interest: To predict the eligible population and the need for total investments to increase the diffusion of rehabilitative treatment of edentulous mandibles in SUS we combined epidemiological information, estimates of participation of the population and treatment costs. The eligible population for treatment with CISP in our study was the same as that for CCP and concerned edentulous mandibles. In Brazil, this condition affects approximately 23 million persons of all age groups, but particularly the elderly (IBGE, 2013). In view of this high prevalence, initially and in the temporal horizon of 5 years, it must be admitted that large scale implementation of CISP is not feasible for 100% of those affected by the condition, for budget reasons. Starting with this reality, we considered that for analysis from the perspective of the Ministry of Health, calculation of the population of interest by the method of demand found was more appropriate for helping with decision making (Brasil, 2012). In 2017, a total of 162,105 Complete Mandibular dental prostheses were approved in Brazil (Brasil, 2017b). This means that this demand exists in the country. From these data, we were able to predict an approximate demand of 900,000 edentulous mandibular patients to be attended over the course of 05 years [temporal horizon of the analysis] in the SUS. Initially, therefore, this would be the eligible population. However, some presuppositions were considered. One of these was that there were contraindications relative to the surgical procedure for implant placement. These limitations included smoker patients, those with some cardiovascular disorders, the use of certain medications and some systemic pathologies (Gómez-de Diego *et al*., 2014). Secondly, we needed to consider that some patients might simply not wish to go through the surgical procedure required. Added to this, there is still the fact that in Brazil, the offer of services included in the public health and private system. So that it was a common occurrence for patients who had economic resources to choose to have treatments they considered more complex performed in the private system. Within this context, we presupposed that only 30% of the total number of patients initially foreseen would fit into the profile of the target population. Considering the initial calculation, we predicted a demand of 270,000 to be attended by means of implant supported prosthesis on two implants, in five years. According to this reasoning, in the new scenario proposed, the patients who met the criteria for rehabilitation with CISP would receive the new treatment, and the remainder would receive CCP.

Reference Scenario and Analysis per Scenarios: The reference scenario of the Budget Impact Analysis considered that all of the 900,000 patients would be rehabilitated with CCPs, while in the scenario proposed, the 270,000 patients eligible for rehabilitation with CISP would receive this treatment and the remainder would be rehabilitated with CCP, as illustrated in Figure 1. Furthermore, in the period of the temporal horizon, it was considered that there would be no increase in the Federal financial transfer value. Analysis per scenarios were made, due to the possibility of the following parameters and presuppositions generating uncertainty in the results:

- Variation in the number of patients to be rehabilitated.
- Variation in the Federal transfer value.

The Federal transfer value and the number of the elected population were simultaneously varied [raised and lowered] by 25%.



Adapted from Sullivan et al (Sullivan et al., 2014). Data from our study

Figure 1 - Illustration showing the difference between the present scenario and the proposed scenarios, considering the temporal horizon of five years

Table 1- Incremental annual budget impact of CISP in relation to CCP for the reference scenario, most optimistic and most pessimistic scenarios from 2020 to 2025, values in in US dollars (Year 2019)

Period	Diffusion	Conventional Complete Prosthesis		Implant-supported Prosthesis		Incremental Budget Impact
		No. of Patients	Impact	No. of Patients	Impact	
Reference Scenario						
2020	10%	27,000	US$ 22,373,666.10	27,000	US$ 119,398,968.00	US$ 97,025,301.90
2021	15%	40,500	US$ 33,560,499.15	40,500	US$ 179,098,452.00	US$ 145,537,952.85
2022	20%	54,000	US$ 44,747,332.20	54,000	US$ 238,797,936.00	US$ 194,050,603.80
2023	25%	67,500	US$ 55,934,165.25	67,500	US$ 298,497,420.00	US$ 242,563,254.75
2024	30%	81,000	US$ 67,120,998.30	81,000	US$ 358,196,904.00	US$ 291,075,905.70
2020-2024	100%	270,000	US$ 223,736,661.00	270,000	US$ 1,193,989,680.00	US$ 970,253,019.00
Most Pessimistic Scenario[a]						
2020	10%	33,750	US$ 34,958,853.26	33,750	US$ 186,560,887.50	US$ 151,602,034.24
2021	15%	50,625	US$ 52,438,279.93	50,625	US$ 279,841,331.25	US$ 227,403,051.32
2022	20%	67,500	US$ 69,917,706.56	67,500	US$ 373,121,775.00	US$ 303,204,068.44
2023	25%	84,375	US$ 87,397,133.19	84,375	US$ 466,402,218.75	US$ 379,005,085.56
2024	30%	101,250	US$ 104,876,559.86	101,250	US$ 559,682,662.50	US$ 454,806,102.55
2020-2024	100%	337,500	US$ 349,588,532.81	337,500	US$ 1,865,608,875.00	US$ 1,516,020,342.40
Most Optimistic Scenario[b]						
2020	10%	20,250	US$ 12,585,187.16	20,250	US$ 67,161,919.50	US$ 54,576,732.34
2021	15%	30,375	US$ 18,877,780.78	30,375	US$ 100,742,879.25	US$ 81,865,098.47
2022	20%	40,500	US$ 25,170,374.36	40,500	US$ 134,323,839.00	US$ 109,153,464.64
2023	25%	50,625	US$ 31,462,967.94	50,625	US$ 167,904,798.75	US$ 136,441,830.81
2024	30%	60,750	US$ 37,755,561.52	60,750	US$ 201,485,758.50	US$ 163,730,196.98
2020-2024	100%	202,500	US$ 125,851,871.81	202,500	US$ 671,619,195.00	US$ 545,767,323.40

In the most optimistic scenario, the population and the transfer values were varied by lowering them, thus calculating a lower impact on the manager. In turn, in the most pessimistic scenario, the population and the transfer values were varied by raising them, thus calculating a higher impact on the manager.

Budget Impact Calculation: Since the difference between the scenarios (actual and proposed) was in the portion of patients treated with CISP and in the value of this treatment, the incremental budget impact was considered the difference between the cost of rehabilitating these patients with CISP and the cost of rehabilitating them with CCP. No adjustment for inflation was considered and the values are presented in US dollars [Year 2019] (Brasil, 2012). The formula applied for calculation is presented below:

$$INI = N \times (C_{CISP} - C_{CCP})$$

Where:
IBI =Incremental Budget Impact
N = Total number of patients with indication for mandibular implant-supported and conventional complete mandibular dental prosthesis.

C_{CISP} = Total Cost of Implant-supported Dental Prosthesis.
C_{CCP} = Total Cost of Conventional Complete Dental Prosthesis.

RESULTS

The incremental budget impact with incorporation of the rehabilitative treatment of mandibular completely edentulous patient by means of implant-supported dentures would be US$ 970,253,019.00 in 5 years in the reference scenario, US$ 545,767,323.40 in the most optimistic scenario, and US$ 1,516,020,342.40 in the most pessimistic scenario (Table 2). This impact must be evaluated according to the budget available to the manager. In this case the resources destined for the technologies evaluated would come from the resources for Medium and High Complexity cases. In 2017, this budget was US$ 65,357,591,614.82 (Brasil, 2017c). By maintaining this value fixed for 5 years, we would have a total of US$ 326,787,958,074.12. Therefore, the budget impact corresponded to 0.29% of the total budget in the reference scenario, 0.46% in the most pessimistic scenario, and 0.16% in the most optimistic scenario.

DISCUSSION

The Ministry of Health foresees Federal transfers to enable the municipalities to offer oral rehabilitation by means of CISP (Brasil, 2010). However, there are few Dental Specialties Centers "Centro de Especialidades Odontológicas" – (CEOs) [only 1.8%] that have professionals working in the area of implant dentistry. Although we recognize the advancement that the offer of these technologies meant for effectuating the integrality of Dental Care in SUS, we have no knowledge of their budget impact analyses. The aim of this BIA was to contribute to the process of planning and management of the technologies evaluated up to the year 2024. Budget impact analyses are becoming increasingly necessary to subsidize decision-making in health, and are routine practice in various countries (Sullivan *et al*., 2014). In SUS, which foresees the offer of universal and integral care, and which has a limited budget, these analyses are even more important. In both the National Policy for Management of Technology in Health, and in Law 12.401/11, Brazil reveals the importance of economic evaluation studies and recommends that budget impact studies should be conducted as support for decision-making in SUS (Brasil, 2012; Brasil, 2011).

In both the reference and alternative scenarios, the values found allowed us to affirm that implementation of the adoption of rehabilitation by means of CPIS was feasible. The technique is considered the best alternative for patients with edentulous mandibles. This indicated the need for adequate planning and management of the budget and government actions to allow the rational use of resources available for public oral health. The protocol for rehabilitation of edentulous mandibles in SUS, for example, must be reviewed. The Federal manager offers financial transfers for encouraging the municipalities to offer implant dentistry services, however, considering the opposite need by the municipal manager, the dissemination of dental implants in the country has been slow. There is also the demand for qualified professionals for treatment with CISP. In this context, in addition to financial investments, political incentive in the spheres of management and education of human resources is imperative for use and dissemination of the technology. One of the principles of SUS that makes economic analysis of the incorporation and dissemination of a certain technology imperative is Universality. The prevalence of mandibular edentulism in the Brazilian population is high, affecting 23 million persons of all ages, a continuing residue of the absence of oral health care over the course of years (Godoi *et al*., 2014; IBGE, 2013). Therefore, offering all edentulous patient CIPS may be unfeasible, due to the financial limitations of the budget. Assuming this reality was necessary for designing the BIA based on the demand found instead of on epidemiology. This fact corroborates the need for investment in policies, such as "Brasil Sorridente" (Smiling Brazil), to prevent perpetuation of scenarios of lack of care and prove their inversion. Relative to the use of the two technologies in SUS, we observed extensive reports in the literature with regard to the difficulty of adaptation to the CCP in the mandible (Das *et al*., 2012; Feine *et al*., 2002; Thomason *et al*., 2009; Vogel *et al*., 2013). Nevertheless, no data were found in SUS about the rate of abandonment of these dentures; that is, there are no estimates of how many patients undergo treatment and do not use the denture, which may be considered a waste of resources from the perspective of SUS as the payer, and would be an important datum to be considered in economic analyses.

Rehabilitation of edentulous patients by means of CISP had a significant effect on the quality of life, when compared with rehabilitation by means of CCP (Sivaramakrishnan & Sridharan, 2016). This change in quality is related to functional improvement, nutritional status and perception of oral health (El Osta *et al*., 2017; Sheiham *et al*., 2001). Improvement in the ingestion of nutritive foods by rehabilitated patients may have effects outside of dental treatment, improving the recovery of general health of patients. CISP is the most cost-effective treatment for rehabilitation of patients with edentulous mandibles even when analyzed from the perspective of the public health manager (Probst *et al.,* 2019) and its dissemination will lead to more benefits to the population. Moreover, it would contribute to avoiding unnecessary expenses with conventional dental prostheses that will be used by the patients. In this sense, the technology deserves to be implemented and extended from the perspective of SUS. The results of this study served to drive and show what the real cost implicated in this treatment is, which is more effective, just and ethical, in view of all the social debt of absence of public policies on oral health in Brazil. This study used parameters of values arising from a cost-effectiveness study and has the same limitations, such as The precise estimate of costs of rehabilitation by means of CISP versus CCP (Probst *et al.,* 2019). Because of the perspective of the Federal Manager adopted, the calculations were based on the table of the SUS [SIGTAP] System of Management of the Table of Procedures, Medications and OPM which, in spite of being limited, indicated that this was the best cost estimate available (Brasil, 2017a). Moreover, the results could not be generalized for the reality of other countries, although the model may be reproduced in other scenarios. Data such as those presented in this study, allied to evidence of cost-effectiveness, have the potential to be a rational basis for decision-making in health. In view of the present budget destined for cases of Medium and High Complexity, the dissemination of rehabilitative treatment performed with CISP was observed to be financially feasible. This concerns the most effective treatment, recognized as the first choice by specialists in the case of patients with edentulous mandibles.

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