Education, Environment and Health Magazine | ISSN 1983-0173

Custo-utilidade de prótese osteointegrada extraoral na reconstrução nasal

Cost-Utility of Extraoral Osseointegrated Prosthesis in Nasal Reconstruction

Costo-utilidad de la prótesis osteointegrada extraoral en la reconstrucción nasal

Rawlson Raoult de Thuin[1]*, Marcelo Daher[2], Antônio Augusto de Freitas Peregrino[3], Andrea dos Santos Garcia[4], Livia de Souza Câmara[5], Cristiano Bertolossi Marta[6], Paulo Ribeiro de Andrade Filho[7], Daniel Aragão Machado[8], Carlos Roberto Lyra da Silva[9], Roberto Carlos Lya da Silva[10]

RESUMO

Objetivo: avaliar o custo-efetividade de prótese osteointegrada extraoral para a correção de deformidades nasais. **Métodos:** avaliação econômica em saúde baseada em modelo de Markov, comparando a cirurgia de retalho facial, sob a perspectiva do SUS. **Resultados:** a cirurgia de retalho resultou em uma razão de custo-efetividade incremental por ano de vida ganho ajustado à qualidade adicional de R$ 2.181,23. **Conclusão:** a cirurgia de retalho é a alternativa custo-efetiva para a reconstrução nasal de pacientes pós-rinectomia no SUS, dependendo da disposição de pagar, já que a razão de custo-efetividade incremental foi menor que o limiar de disposição de pagar.

DESCRITORES: Reconstrução nasal; Avaliação de custo-efetividade; Cirurgia plástica; Prótese nasal.

ABSTRACT

Objective: to evaluate the cost-effectiveness of extraoral osseointegrated prosthesis for the correction of nasal deformities. **Methods:** economic evaluation in health based on a Markov model, comparing facial flap surgery, from the SUS perspective. **Results:** facial flap surgery resulted in an incremental cost-effectiveness ratio per additional quality-adjusted life year gained of R$ 2,181.23. **Conclusion:** facial flap surgery is the cost-effective alternative for nasal reconstruction in post-rhinotomy patients in the SUS, depending on the willingness to pay, as the incremental cost-effectiveness ratio was lower than the willingness-to-pay threshold.

DESCRIPTORS: Nasal reconstruction; Cost-effectiveness evaluation; Plastic surgery; Nasal prosthesis.

[1]Universidade Federal do Estado do Rio de Janeiro. Rio de Janeiro - RJ. * plasticario@gmail.com
[2] Interclínica-Centroplástica. Rio de Janeiro - RJ.
[3,6]Universidade do Estado do Rio de Janeiro. Rio de Janeiro - RJ.
[4]Empresa Pública de Saúde do Rio de Janeiro (RioSaúde). Rio de Janeiro - RJ.
[7]Empresa Brasileira de Serviços Hospitalares. Rio de Janeiro - RJ.
[8,9,10] Universidade Federal do Estado do Rio de Janeiro. Rio de Janeiro – RJ.

RESUMEN

Objetivo: evaluar la rentabilidad de la prótesis extraoral osteointegrada para la corrección de deformidades nasales. **Métodos:** Evaluación económica en salud basada en un modelo de Markov, comparando la cirugía de colgajo facial, desde la perspectiva del SUS. **Resultados:** la cirugía de colgajo resultó en una razón de rentabilidad incremental por año de vida ganado ajustado por calidad adicional de R$ 2.181,23. **Conclusión:** la cirugía de colgajo es la alternativa rentable para la reconstrucción nasal en pacientes post-rinectomía en el SUS, dependiendo de la disposición a pagar, ya que la razón de rentabilidad incremental fue menor que el umbral de disposición a pagar.

DESCRIPTORES: Reconstrucción nasal; Evaluación de rentabilidad; Cirugía plástica; Prótesis nasal.

INTRODUCTION

When it comes to facial reconstructions, aesthetic results, although still technically undervalued compared to functional ones, are outcomes that may interest patients much more than professionals due to their importance in the social reintegration process of these people after reconstruction (Elmelegy et al., 2019, p. 195-199).

Considering outcomes that interest patients, both nasal reconstruction surgery and the use of prostheses are alternatives available in the SUS that can provide patients with facial mutilations with satisfactory aesthetic results.

Total or partial nose reconstruction surgery is a procedure offered by the SUS and is registered in the SUS Procedures, Medications, and OPM Management System (SIGTAP), with the code 04.04.02.024-0.

Rehabilitation with prostheses is an alternative to facial flap surgery for facial surgical reconstruction, such as the extraoral osseointegrated nasal prosthesis (SIGTAP code 07.01.08.017-5).

The extraoral osseointegrated nasal prosthesis is described as a prosthesis for nasal replacement that must be fixed by extraoral osseointegrated implants. It is a technology still little used among plastic surgeons in Brazil and more widespread among dentists and maxillofacial surgeons (Volpato et al., 2016).

Incorporating prostheses into the facial rehabilitation resources arsenal of plastic surgeons can represent additional benefits to the patient, such as the simplicity in the execution of the technique, lower risk, and shorter return time to work activities. For the health system, it can

represent lower cost when compared to flap surgery, which is performed on average three (3) times at a minimum (Rodrigues, 2005).

OBJETIVO

The objective of this study is to evaluate whether the extraoral osseointegrated prosthesis is a cost-effective alternative for the reconstruction of nasal deformities in the SUS.

MATERIALS AND METHODS

A cost-utility analysis was performed based on a dynamic analytical model of the Markov Chain type. The model was developed and analyzed using the Treeage Pro Healthcare 2021® software to estimate the incremental cost-effectiveness ratio of using extraoral osseointegrated prosthesis compared to flap surgery for the reconstruction of nasal deformities caused by skin cancer in the SUS.

To increase the transparency of the proposed study, the main aspects of the study were summarized according to the CHEERS Task Force Reforce checklist (Husereau, 2013, p. 231-250) (Frame1).

Table 1 - Characteristics of the proposed analytical model

Background and objectives	The objective of this cost-utility economic analysis based on a Markov model is to evaluate whether the use of extraoral osseointegrated prosthesis compared to flap surgery for the reconstruction of nasal deformities caused by mutilating diseases such as skin cancer is cost-effective.
Target population	Adult patients of both sexes aged 67 years or older with nasal mutilations caused by cancer.
Perspective of analysis	Unified Health System (SUS)
Comparators	Flap surgery
Time horizon	1 year with 2 half-yearly cycles
Discount rate	Not applied
Effectiveness measures	Quality-adjusted life years (QALY)
Cost estimates	Only direct medical costs
Currency	Real ($)
Chosen model	Markov model
Sensitivity analysis	Deterministic (Tornado diagram) and probabilistic (Monte Carlo simulation)

Outcome probabilities

The probability of success and failure (022) in surgery was estimated from the complication rate. The proportion of patients who had any complication was considered a failure regardless of the stage of surgery in which the complication occurred (Lima; Rocco, 2007). The mortality rate due to non-melanoma skin cancer was referenced in a study by Barton et al. (2017, p. 243-251) which reported RR. 104: 95% CI (1.01–1.06).

Effectiveness of interventions

The quality-adjusted life years (QALY) were extrapolated from the international scientific literature since no national studies reporting the impact of the disease on the quality of life of the Brazilian population were identified (Frame 2).

Frame2 - Health state utility estimates considered in the model

Condition	Utility
Patient undergoing reconstruction surgery	0,89 (±0,13)
Patient using extraoral osseointegrated prosthesis	0,82 (±0,20)
Patient with nasal deformity	0,74 (±0,24)

Source: Faris study (2019) (https://doi.org/10.1002/LARY.28480).

Cost of interventions

Only direct medical costs were considered. All costs were extracted from the SUS Procedures Management System - SIGTAP of the Ministry of Health and are presented in Table 1.

Table 1. Costs of procedures offered in the SUS

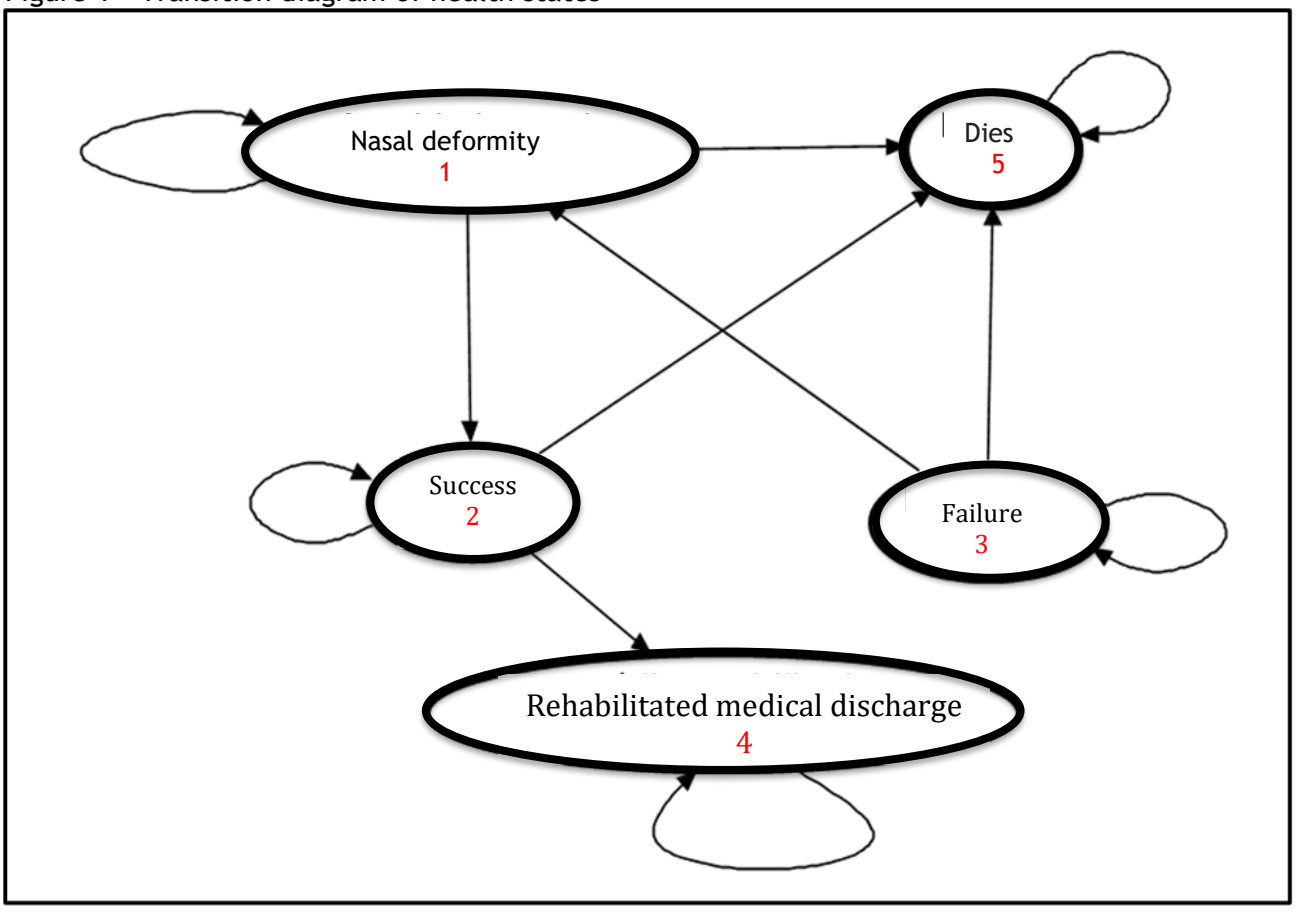
SIGTAP code	Procedure	Values
04.04.02.024-0	Flap surgery	R$ 397,38
03.03.08.009-4	Treatment of other skin and subcutaneous tissue conditions	R$ 202,24
07.01.08.017-5	Extraoral Osseointegrated Prosthesis	R$ 650,00
03.01.07.012-1	Intensive treatment of patients in physical rehabilitation	R$ 21,69
03.01.01.004-8	Consultation of higher-level professional in specialized care (except maxillofacial surgeon)	R$ 6,30
03.01.01.007-2	Medical consultation in specialized care	R$ 10,00
03.08.04.001-5	Treatment of complications from surgical or clinical procedures	R$ 199,33

Source: SUS Procedures Management System - SIGTAP 2021.

The Analytical Model

In the transition diagram between the health states assumed in the model, the arrows represent possible transitions between health states (Figure 1).

Figure 1 - Transition diagram of health states



Source: Prepared by the author (2022).

Patients enter the analytical model (Figure 2) with craniofacial mutilation involving part or all of the nose with an indication for aesthetic repair either through flap surgery or through extraoral osseointegrated prosthesis.

Once it is defined how the patients' nasal deformities will be corrected, patients enter the Markov cohort and may maintain the deformity after the procedure, may have the deformity corrected after the procedure, may be discharged after the deformity is corrected and rehabilitation is completed, or may die.

Assumptions made in the model

1- All patients who populated the Markov model have advanced-stage skin cancer and are carriers of mutilating craniofacial lesions involving the nose;

2- The probability of the patient opting for surgery, or it being recommended by the professional is the same in relation to the prosthesis;

3- All patients will undergo a single biannual surgical intervention and a single annual prosthetization;

4- All patients will be followed up through two biannual medical consultations with a plastic surgeon and two biannual consultations with a maxillofacial dentist;

5- In relation to health states, the model considered as medically rehabilitated discharge patients who completed follow-up and were successful and are rehabilitated both after surgery and after the placement of the prosthesis;

6- Patients who were unsuccessful in the procedures and had surgical complications or skin conditions will continue with the nasal deformity;

7- Death from disease complications was referenced to the probability of death from non-melanoma skin cancer regardless of sex and age;

8- For death from surgical complications, the probability of death from liposuction surgery was considered since estimates related to flap surgery were not found;

9- Cost parameters were varied by 30% in sensitivity analyses to include uncertainties in the parameters of the variables input into the model;

10- Transition and outcome probabilities were varied by 20% in sensitivity analyses to include uncertainties in the parameters of the variables input into the model.

Variables and parameters input into the Model

The variables input into the model, their descriptions, and their respective parameters are presented in Table 2.

Table 2. Variables and their respective parameters

Name	Variable Description	Mean	Minimum	Maximum	SD	Reference
C_Afec_pel	Cost of skin conditions	202,00	141,00	262,00	85,5	SIGTAP
C_Cir	Cost of surgery	397,00	278,00	516,00	168,2	SIGTAP
C_Comp_Cir	Cost of complications	199,00	139,00	259,00	84,8	SIGTAP
C_Cons_Bmxf	Cost of maxillofacial consultation	6,30	4,41	8,19	2,6	SIGTAP
C_Cons_Med	Cost of medical consultation	10,00	7,00	13,00	4,2	SIGTAP
C_Peo	Cost of extraoral prosthesis	650,00	450,00	845,00	279,3	SIGTAP
C_Reab_Fis	Cost of physical rehabilitation	43,00	30,00	55,00	17,6	SIGTAP
P_Mort_CNM	Probability of cancer death	0,04	0,01	0,06	0,04	Kahn, 1998
P_Prot_Ope	Probability of reconstruction	0,786	0,63	0,94	0,22	Chipp, 2011
P_Suc_Cir	Probability of surgery success	0,78	0,62	0,94	0,22	Ting-Ling, 2005
P_Suc_Prot	Probability of prosthesis success	0,92	0,89	0,95	0,04	Ting-Ling, 2005
U_Cir	Surgery utility	0,89	0,76	1,00	0,17	Faris, 2019
U_Pos_Rinec	Post-rhinotomy utility	0,74	0,50	0,98	0,34	Faris, 2019
U_Prot	Prosthesis utility	0,82	0,62	1,00	0,27	Faris, 2019

Source: Prepared by the author (2022).
Notes: Costs in Reais (R$). SD = Standard Deviation. SIGTAP = SUS Procedures Management System. Source: http://sigtap.datasus.gov.br/tabela-unificada/app/sec/inicio.js

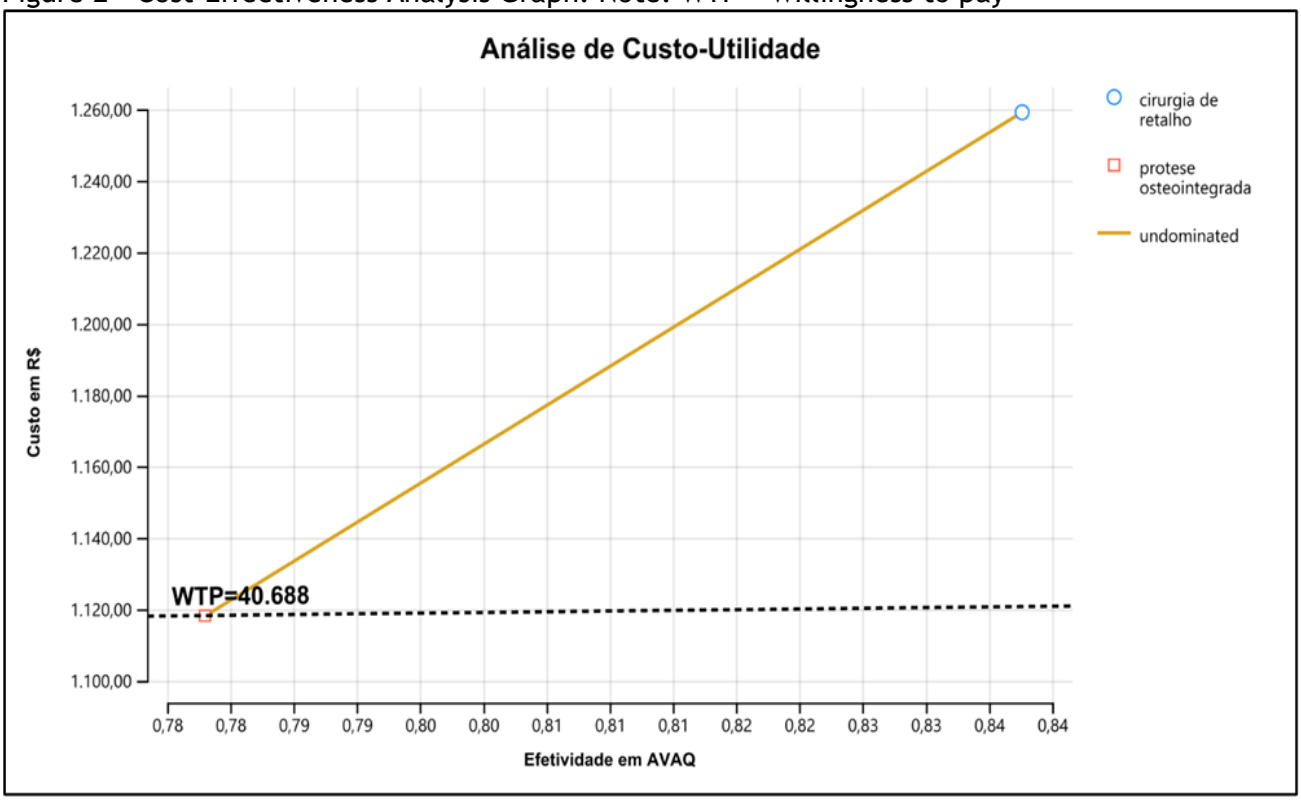
RESULTS

The cost-utility analysis results suggest that both flap surgery and the use of osseointegrated prosthesis may be cost-effective depending on the willingness to pay (Figure 2).

The option for flap surgery for the reconstruction of nasal deformities in the SUS may result in an incremental cost per quality-adjusted life year gained demonstrated by the Incremental Cost-Effectiveness Ratio (ICER) estimated at R$ 2,181.23.

In the cost-utility analysis graph (Figure 2), the oblique line connecting the two interventions analyzed in the base case represents the uncertainty considering the incremental cost-effectiveness ratio and the willingness to pay threshold set at R$ 40,688.00 in relation to available alternatives.

Figure 2 - Cost-Effectiveness Analysis Graph. Note: WTP = willingness to pay



Source: Prepared by the author (2022).

In practice, the uncertainty revealed by the model refers to the following question: Should the alternative that represents higher cost but higher effectiveness in this case, flap surgery (represented in the graph by the blue circle located at the top right), or the alternative that represents lower cost but lower effectiveness in this case, extraoral osseointegrated prosthesis (represented in the graph by the red square located below and to the left). The choice should therefore take into account the willingness to pay.

Sensitivity analysis

The multivariate deterministic sensitivity analysis showed that none of the model's variable parameters could modify the cost-utility analysis results.

The results of the probabilistic sensitivity analysis show that surgery is the alternative with the highest proportion of cost-effective iterations in 10,000 Monte Carlo simulations. The oblique dotted line (WTP) represents the willingness to pay threshold.

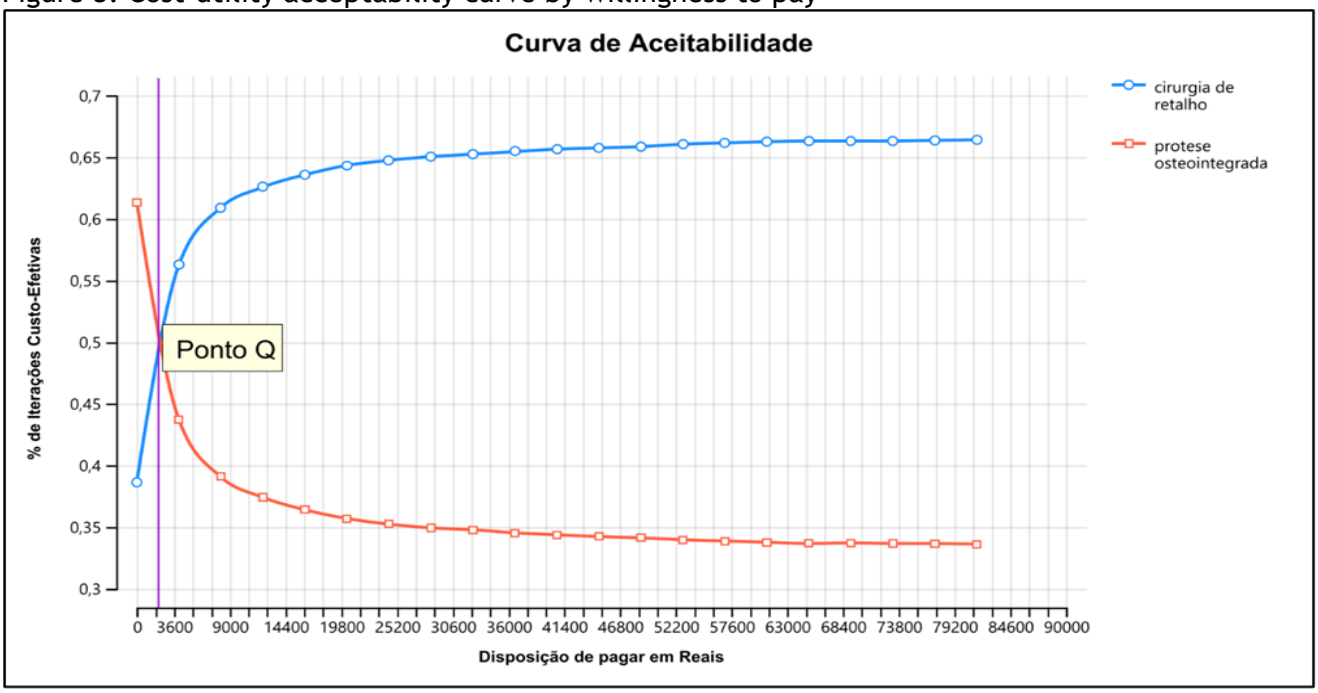
Table 3 presents the results of 10,000 Monte Carlo Simulations where it is possible to observe that the proportion of interactions favorable to surgery (Components C1, C2 and C5) can reach 0.769, considering the willingness to pay threshold of up to R$40,688, 00. Therefore, probabilistically, surgery is more likely to be cost-effective in the base case than extraoral prosthesis.

Table 3. Report of Monte Carlo simulation results

Component	Quadrant	Efe Incr	Incr Efec	Incr RCEI	Frequency	Proportion
C1	IV	IE>0	IC<0	Superior	2564	0,2564
C2	I	IE>0	IC>0	ICER<40688.0	3915	0,3915
C3	III	IE<0	IC<0	ICER>40688.0	85	0,0085
C4	I	IE>0	IC>0	ICER>40688.0	252	0,0252
C5	III	IE<0	IC<0	ICER<40688.0	1217	0,1217
C6	II	IE<0	IC>0	Inferior	1967	0,1967

Source: Prepared by the author (2022). Note: ICER = Incremental Cost-Effectiveness Ratio. Inc = Incremental. Efe = Effectiveness. IE = Increment of effectiveness. IC = Increment of cost. Costs in Reais.

Figure 3. Cost-utility acceptability curve by willingness to pay



Source: Prepared by the author (2022).

A cost-utility acceptability curve (Figure 3) was plotted based on the Monte Carlo simulation results to estimate the probability that each intervention has of being cost-effective in the base case considering the variation of the willingness to pay threshold per additional unit of effectiveness (ICER).

The purple line represents point Q. At this point, if the willingness to pay is approximately R$ 2,100.00, the alternatives will have the same probability of being cost-effective. However, from this value, surgery becomes more likely to be cost-effective compared to the prosthesis.

The graph also shows that a willingness to pay above R$ 81,376.00 will no longer represent any increase in the probability of surgery being cost-effective, not exceeding 0.664.

DISCUSSION

The reconstruction of nasal mutilations is challenging for both the surgeon and the prosthetist since both techniques have distinct limitations in terms of indication, effectiveness, and costs, as well as the technical skills of the professionals involved.

Prosthetic rehabilitation can have some advantages, such as the ability to observe the area that underwent surgery for healing and disease recurrence, improved aesthetics, simplicity of the technique, and overall low cost, but as the model suggested, it is not the most cost-effective

alternative, which of course needs to be considered when the analysis is done from the SUS perspective.

Although extraoral osseointegrated prosthesis may play the role of rehabilitating these patients, making them more socially adept, it involves costs and consequences that deserve to be analyzed from an economic perspective, considering that these prostheses are still little known, researched, and valued both in organizations and in the academic environment, as suggested by the scarcity of studies on this topic.

It is necessary to highlight that for the choice between surgical and prosthetic approach in the case of nasal mutilation, besides the aspects already highlighted such as the amount of remaining support tissue, age, and health status of the patient, and pathological findings, it is essential to consider the available human resources and the necessary skills for both surgical and prosthetic reconstruction.

It is also important to note that surgical reconstruction and prosthetic rehabilitation can be used together when neither alternative alone achieves the maximum aesthetics and function, but this of course depends on an evaluation not only by the plastic surgeon and the multidisciplinary team involved but above all by the patient themselves.

Accurate measurement methods that comprehensively assess the effects of the best treatment for individuals with nasal deformities from outcomes that interest patients need to be more valued. Decisions about performing surgical and non-surgical procedures are often made solely based on study results that reported clinical outcomes that interest professionals much more than patients.

Post-rhinotomy surgical approach may be the cost-utility profile alternative available in the SUS, but this is only valid for selected cases in the absence of contraindicating conditions or due to the patient's choice among the alternatives presented to them.

According to Goiato (2005), the satisfaction of patients undergoing only surgical treatment after rhinotomy is low, and therefore most of them are not satisfied with their appearance, and all have some aesthetic complaints about the surgical area, reinforcing the need to seek to expand knowledge about the use of prostheses as an alternative to surgery that can be cost-effective in the SUS.

It should be considered that since the beginning of plastic surgery, there has been a link between repair and aesthetic sense, between reconstructing aesthetics and returning to social life,

between restoring function and concern with the shape of the affected part, even when these changes result from processes seen as physiological such as pregnancies and aging. The history of plastic surgery is therefore linked to reconstructive surgery because their techniques are complementary. This may help to understand the reasons why nasal deformity reconstruction surgery presents greater utility than prosthesis.

It does not matter the etiology of the deformity. Whether due to trauma, disease, or physiological evolution, the effect on the patient's self-image is usually equally harmful. Specialists indicate an aesthetic procedure taking into account the psychological repair of the patient, applying the concept that all aesthetic surgery is restorative as it repairs not only the physical but also psychological problems such as psychological trauma, inhibitions, and complexes (POLI NETO; CAPONI, 2007, p. 569-584).

As a rule, the notion of cost-effectiveness and cost-utility seems to be a secondary concern, obviously depending on the nature of the health institution, whether public or private.

Whatever technology is used, it is possible to imagine how much patients with nasal mutilations would like to improve their appearance, making it less negatively impactful for them and the people around them, and this is relevant because body image has a great impact on people's emotions, thoughts, and behavior. Likewise, it is also important to emphasize that this has a financial cost, and therefore it is necessary to carefully evaluate the size of the benefit that the procedure can provide and whether these justify the costs for its achievement.

Plastic surgeons know that concerns with their own body, when they exist, are difficult to resist and control, potentially causing many irreversible psychological sufferings. These people seek plastic surgery to minimize their mutilations, improve their appearance, and self-image (Tomas-Aragones; Marron, 2016, p. 47-50).

Model Limitations

Given that only parametric and second-order uncertainties were explored in the sensitivity analysis, the results of this cost-utility analysis should be used with caution, especially in terms of external validity.

The utilities of rhinotomy, surgery, and prosthesis in the Brazilian population are uncertain, given that these measures were extrapolated from studies conducted with individuals in countries with very different characteristics from Brazil, especially in terms of human development index, quality, and life expectancy. This should be considered an important limitation of this Thesis.

Structural uncertainties related to the model structure as well as analytical uncertainties related to how the analysis was done, whether based on microsimulation or cohort, or deterministic model (decision tree), for example, were not explored in sensitivity analyses.

There are also uncertainties regarding the costs of each of the interventions and scenarios analyzed, considering that some costs were not incorporated into the model, as stated in the assumptions, such as costs with re-operations, re-prostheses, and rehospitalizations, for example.

CONCLUSION

The analytical model suggests that frontal flap surgery is more likely to be the most cost-effective alternative for the reconstruction of nasal deformities in post-rhinotomy patients in the SUS, although it depends on the willingness to pay.

In this sense, if the manager is willing to pay for these patients to gain one more quality-adjusted life year an amount of R$ 2,181.23 (two thousand one hundred and eighty-one reais and twenty-three cents), surgery becomes more cost-effective and tends to increase this advantage over the prosthesis in terms of probability of being cost-effective the greater the willingness to pay, reaching the maximum probability with a willingness to pay of approximately R$ 81,376.00 (eighty-one thousand three hundred and seventy-six reais).

It should be highlighted that the model results significantly disfavored the extraoral osseointegrated prosthesis, considering that it was not possible to use utility estimates of the interventions in the national context. Therefore, it is questionable whether the results would have been different if it had been possible to use patient satisfaction or the utility attributed by them for each of the interventions in the SUS context.

REFERENCES

1- ARAGONES, Lucia Tomas.; MARRON, Servando. Body Image and Body Dysmorphic Concerns. **Acta Derm. Venereo**, n. 217, v. 96, p. 47-50, 2016. Disponível em: https://doi.org/10.2340/00015555-2368. Acesso em: 18-mai. 2022.

2- BARTON, Virginia; ARMESON, Kent; HAMPRAS, Shalaka; FERRIS, Laura; VISVANATHAN, Kala; ROLLISON, Dana; ALBERG, Anthony. Nonmelanoma skin cancer and risk of all-cause and cancer-related mortality: a systematic review. **Archives of dermatological research**, n. 4, v. 3, p. 243-251, 2017. Disponível em: https://doi.org/10.1007/s00403-017-1724-5. Acesso em 18-mai. 2022.

3- ELMELEGY, N; ELGHAMRY, S; SHOUKR, T. Free Style Perforator Flaps for Aesthetic Facial Reconstruction. **World Journal of Plastic Surgery**, v. 8, n. 2, p. 195-199. Disponível em: https://doi.org/10.29252/wjps.8.2.195. Acesso 07-jun. 2022.

4- FARIS, Callum; HEISER, Alyssa; QUATELA, Olivia; JACKSON, Matthew; TESSELER, Oren; JOWETT, Nate; LEE, Linda N. Health utility of rhinectomy, surgical nasal reconstruction, and prosthetic rehabilitation. **Facial Plastics/Reconstructive Surgery**, n. 7, v. 130, 2019. Disponível em: https://doi.org/10.1002/LARY.28480. Acesso em 07-abr. 2022.

5- GOIATO, MC, FERNANDES, AÚR, TREVISAN, CL, CONRADO, Neto, S. Reconstrução da pirâmide nasal com prótese. Rev. ABO Nac 2005;13:166-70.

6- HUSEREAU, Don; DRUMMOND, Michael; PETROU, Stavros; CARSWELL, Chris; MOHER, David; GREENBERG, Dan, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) - explanation and elaboration: a report of the ISPOR Health Economic Evaluation Publication Guidelines Good Reporting Practices Task Force. **Value Health**, n. 2, v. 16, p. 231-250, 2013. Disponível em: https://doi.org/10.1016/j.jval.2013.02.002. Acesso em: 18-mai. 2022.

7- LIMA, Ricardo; ROCCO, Patrícia. Cirurgia para controle do dano: uma revisão. **Rev. Col. Bras. Cir**, n. 5, v. 34, 2007. Disponível em: https://doi.org/10.1590/S0100-69912007000500008. Acesso em 18-mai. 2022.

8- POLI NETO, Paulo; CAPONI, Sandra. A medicalização da beleza. **Interface: Comunic, Saúde, Educ, Florianópolis**, n. 23, v. 11, p. 569-584, 2007. Disponível em: https://doi.org/10.1590/S1414-32832007000300012. Acesso em: 18-mai. 2022.

9- RODRIGUES, Shobha; SHENOY, Vidya Kamalaksh. Prosthetic rehabilitation of a patient after partial rhinectomy: a clinical report. **J Prosthet Dent**, n. 2, v. 93, p.125-128, 2005. Disponível em: https://doi.org/10.1016/j.prosdent.2004.10.021. Acesso em: 20-sep. 2021.

10- VOLPATO, Luiz Evaristo Ricci; VOLPATO, Maria Carmen Palma Faria; CARVALHO E SILVA, Lucas Antonio; CASTRO, Paulo Henrique de Souza; BORGES, Alvaro Henrique. Prótese nasal óculo-suportada. **Revista Cubana de Estomatología**, n. 3, v. 53, p. 146-152, 2016. Disponível em: https://www.redalyc.org/journal/3786/378663190010/html/. Acesso em: 18-mai. 2022.