# Financial impact on glaucoma surgical treatment

Impacto financeiro no tratamento cirúrgico do glaucoma

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# Abstract

**Objective:** The second leading cause of blindness worldwide, glaucoma, occasionally requires surgical procedure for control. Given that Brazil has an Unified Health System (SUS) and a political-economic crisis in 2016, we aim to evaluate the financial impact on the therapeutic decision of glaucoma in the last 6 years in Brazil, and to consider the current discussion about early interventionist indication in its therapeutic algorithm. **Methods:** Ecological study of the Brazilian population, based on the SUS Hospital Information System, evaluating the temporal behavior of SUS surgical procedures on glaucoma treatment, and dollar variation as influencing the temporal trend on the procedures. Simple Linear Regression analysis was performed, with statistical significance of P < 0.05. **Results:** Between 2013 and 2018, 24888 individuals were hospitalized for glaucoma, male prevalence (51.68%), whites (32.57%) and elderly (57.84%). Southeast (45.61%) and Northeast (26.36%) Regions with the largest number of hospitalizations, and Trabeculectomy (84.18%) being the main procedure performed. There was an association of trabeculectomy and valve implantation, individually and linked, with dollar values in the Midwest ( $\beta = 1.103$  with P = 0.007 for Trabeculectomies and  $\beta = 1.105$  with P = 0.012 for both procedures) and South ( $\beta$ ). = 16,727 and P = 0,006 for Implants), and association between increased Implants in the South region and greater coverage in primary care ( $\beta = 0.64$  and P = 0.009). **Conclusion:** Non-dollar interference was observed, and increased procedures provided by the SUS in an early manner.

Keywords: Costs and cost analysis; Filtering surgery; Glaucoma; Glaucoma drainage implants; Prosthesis implantation; Brazil

# Resumo

**Objetivo:** Segunda maior causa de cegueira mundial, o glaucoma, ocasionalmente necessita de procedimento cirúrgico para controle. Tendo o Brasil um Sistema Único de Saúde (SUS), e crise político-econômica em 2016, objetiva-se avaliar o impacto financeiro na decisão terapêutica do glaucoma nos últimos 6 anos no Brasil, e considerar atual discussão sobre indicação de procedimentos intervencionistas precocemente no seu algoritmo terapêutico. **Métodos:** Estudo ecológico da população brasileira, com base no Sistema de Informações Hospitalares do SUS, avaliando comportamento temporal dos procedimentos cirúrgicos do SUS para tratamento do glaucoma, e variação do dólar como influenciador da tendência temporal sobre os procedimentos. Realizada a análise de Regressão Linear Simples, com significância estatística de P<0.05. **Resultados:** Entre 2013 e 2018 foram internados 24888 indivíduos por glaucoma, prevalência do sexo masculino (51.68%), brancos (32,57%) e idosos (57.84%). Regiões Sudeste (45.61%) e Nordeste (26.36%) com maior número de internações, sendo a Trabeculectomia (84,18%) principal procedimento realizado. Houve associação da Trabeculectomia e Implante de Válvula, individualmente e atrelados, com os valores do dólar nas regiões Centro-Oeste ( $\beta$ = 1,103 com P= 0,007 para Trabeculectomias e  $\beta$ = 1,105 com P=0,012 para ambos os procedimentos) e Sul ( $\beta$ = 16,727 e P= 0,006 para os Implantes), e associação entre aumento de Implantes na região Sul e maior cobertura na atenção básica ( $\beta$ = 0.64 e P= 0.009). **Conclusão:** Observou-se não interferência do dólar, e aumento dos procedimentos na região Sul e Centro-Oeste. Os resultados corroboram tendência intervencionista, podendo ser representada pelo possível uso dos procedimentos disponibilizados pelo SUS de forma precoce.

Descritores: Custos e análise de custo; Cirurgia filtrante; Glaucoma; Implantes para drenagem de glaucoma; Implantação de prótese; Brasil

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## INTRODUCTION

ccording to the latest data made available by the World Health Organization, <sup>(1)</sup> glaucoma is one of the leading causes of blindness worldwide (12.3%) - it is only second to cataracts (47.8%) - and the main cause of irreversible blindness cases in Brazil and worldwide. <sup>(2)</sup> According to estimates, there will be 79.6 million individuals with open- and closed-angle glaucoma in 2020.<sup>(3)</sup>

Despite the technological and scientific advancements in glaucoma diagnosis and treatment, its delayed diagnosis or inadequate disease management, either by the physician or due to poor access to the health system, can worsen patients' conditions and lead to permanent injuries, regardless of the available treatments. <sup>(4-6)</sup> Public treatment is made available for glaucoma patients through the Brazilian Unified Health System (SUS – Sistema Único de Saúde), which is one the largest national health systems in the world <sup>(7)</sup>, despite the lack of public funding, misallocation of resources and other shortcomings observed in its services.<sup>(8,9)</sup>

Glaucoma treatment often starts with clinical therapy based on antiglaucomatous eye drops. However, invasive procedures are recommended when this therapy is no longer effective in controlling intraocular pressure.<sup>(10)</sup>

The approach to glaucomatous patients is not satisfactorily performed, since 89% of diagnosed cases present disease progression. <sup>(11)</sup> Even patients subjected to clinical treatment, in clinical trials, presented disease progression: 34% of untreated patients and 20% of treated patients followed-up for 24 months presented disease progression. <sup>(12)</sup> One of the reasons for such an outcome may lie on poor therapeutic adherence, which ranged from 4.6% to 80%, as well as on non-persistence to treatment for 12 months, whose rate ranged from 50% to 75%.

Trabeculectomy is one of the invasive procedures used to treat glaucoma; this fistulizing surgery has the advantage of reducing pressure fluctuations to enable intraocular pressure stability. <sup>(13)</sup> However, it may lead to several complications - such as infections, postoperative hypotonia and scarred bleb <sup>(14)</sup> - capable of limiting its long-term effectiveness.

Valve implantation surgery is another form of invasive treatment available for glaucoma patients at SUS; it is often used to treat refractory glaucoma, as well as after trabeculectomy, or after any other surgery that has failed to control the intraocular pressure. <sup>(15,16)</sup> However, it is worth emphasizing that the surgical manipulation of the conjunctiva to place the drainage device may render future trabeculectomy unfeasible in case of implantation failure. <sup>(17)</sup>

Trabeculectomy and tube implantations are often indicated at a much later stage in glaucoma treatment due to their potential to lead to severe short- and long-term complications. <sup>(16,18,19)</sup>

There are less invasive procedures available nowadays, such as the "microinvasive or minimally invasive glaucoma surgery" (MIGS). Although these procedures do not have a strict definition, they are featured by minimal external dissection, short operative time, good safety profile and rapid recovery. <sup>(20)</sup> In addition, they optimize the safety of surgical interventions applied to glaucoma patients, <sup>(21)</sup> which enables using them early in the therapeutic paradigm and in non-refractory glaucoma cases. <sup>(22,23)</sup>

Instead of competing with traditional filtering surgeries, MIGSs are an alternative to excessive drug therapy, since they mitigate therapeutic issues attributed to medication, such as adverse effects, poor therapeutic adherence and low quality of life. <sup>(21-23)</sup> Based on the Brazilian public health reality observed at SUS and on procedures made available by it, it is necessary taking into consideration the cost with the adopted procedure rather than just analyzing patients' clinical conditions to enable therapeutic decisions between trabeculectomy and implant, since the need for the implantable device can burden the public system, and it may delay the authorization and performance of higher cost procedures.

The price of the implantable device has increased in the last few years; consequently, so did the cost with tube-shunt surgery, which went from R\$ 499.20 in 2013 to R\$ 873.61 in 2018 <sup>(24)</sup> – this period corresponds to the appreciation of the US dollar against the Brazilian Real <sup>(25)</sup>, which reached its peak in 2016. The recorded increase in the aforementioned price was triggered by the political-economic crisis that took place in Brazil in 2016, which led to the biggest accumulated GDP drop in the Brazilian history (more than 7%), as well as to an exchange rate shock that devaluated the Brazilian currency by 50% against the US dollar, with variation from 2.63 R\$/US to 4.05 R\$/US\$. <sup>(25)</sup> In addition, unemployment rate increased from less than 7% in 2014 to over 13% in 2016. <sup>(26)</sup>

Based on the similar efficacy between trabeculectomy and tube-shunt surgery <sup>(20)</sup>, which are therapeutic options available at SUS and the public system's alternative to MIGS, as well as on the current debate about the recommendation of interventionist procedures to both early and refractory cases, the aim of the current study was to evaluate the financial impact - at hospital level - on therapeutic decisions concerning glaucoma patients in Brazil, in the last 6 years.

#### **Methods**

Ecological study conducted with the Brazilian population in order to evaluate the epidemiological profile of hospitalizations due to glaucoma in the Brazilian Unified Health System (SUS), as well as to identify the temporal behavior of surgical procedures adopted to treat the disease from 2013 to 2018, by associating them with US dollar fluctuations and with Primary Care coverage. Epidemiological profile was based on the calculation of hospitalization rates whose basic cause was described as Glaucoma (ICD-10 H.40) in Hospital Admission Orders (HAO). These HAOs were stratified by sex, race/color and age group; data were collected in SUS's Hospital Information System (SIH/SUS - Sistema de Informações Hospitalares do SUS).

The object of the current study was defined as the procedures most often performed by SUS to correct glaucoma, namely: Trabeculectomy (04.05.05.032-1) and Anti-Glaucomatous Prosthesis Implant (04.05.05.013-5). Next, the number of procedures (SIH/SUS) was tabulated, both together and in separate, according to the investigated years and to Brazilian regions. Subsequently, procedure rates were calculated based on the quotient between the number of procedures and the resident population (according to sex- and age-group-based population projections recorded for Federation Units by the Brazilian Institute of Geography and Statistics - IBGE), multiplied by 100 thousand inhabitants.

The Ministry of Health's Primary Care e-Manager website (https://egestorab.saude.gov.br/) was used to evaluate the monthly primary care (PC) coverage in each region throughout the investigated years in order to enable calculating the mean annual coverage per region. In addition, the annual dollar variation – i.e., the annual mean value of the currency made available by Ipeadata (http://www.ipeadata.gov.br/) - was set as the factor influencing the time trend to carry out the procedures.

Simple Linear Regression analysis was carried out to find the association between the performance of the investigated procedures and Primary Care coverage, or the annual value of the dollar. It resulted in the slope coefficient  $\beta$  of the line. Statistical significance was set at P < 0.05.

Data were tabulated in the TabWin software and calculations were carried out in Excel software. All analyses were carried out in Stata statistical package v. 14.0.

### RESULTS

The total of 24,888 individuals were hospitalized due to glaucoma from 2013 to 2018; 51.68% of them were men and 48.32% were women. Of these, 9,298 did not have information about parameter "race/color". Based on Table 1, most patients were Caucasian (white) (32.57%); they were followed by mixed ethnic ancestry (brown) individuals (22.65%). Elderly individuals (57.84% of cases) were the main population hospitalized due to Glaucoma; they were followed by adult individuals (34.06% of cases). The largest number of hospitalizations per region was observed in the Southeastern region (45.61%), which was followed by the Northeastern region (26.36%).

Table 2 shows both corrective procedures; 18,792 of them were notified, 47.52% were performed in the Southeastern region and 26.80%, in the Northeastern region (the two main highlighted regions). Trabeculectomy was the main procedure performed in separate (84.18%).

Based on the comparison of equivalent periods in the past to the herein investigated period, which was divided into triennia, the number of procedures increased, as shown in Figure 1. The first triennium (2009-2011) presented mean annual variation

Table 1				
Epidemiological and demographic profile				
of hospitalizations due to Glaucoma in the				
Brazilian Unified Health System				

Variable	n	%
Sex		
Female	12,027	48.32
Male	12,861	51.68
Age group		
0-14 years (children)	1,726	6.94
15-19 years (teenagers)	289	1.16
20-59 years (adults)	8,477	34.06
60 years or older (elderly)	14,396	57.84
Race / Color		
Caucasian	8,105	32.57
African-descendant	1,532	6.15
Mixed ethnic ancestry	5,637	22.65
Asian-descendant	314	1.26
Indigenous	2	0.01
No information	9,298	37.36
Region		
Central-Western	2,004	8.05
Northeastern	6,560	26.36
Northern	265	1.07
Southeastern	11,352	45.61
Southern	4,707	18.91

Source: Tabulation and calculations carried out by the au

#### Table 2

Absolute and relative frequency of procedures such as trabeculectomy, antiglaucomatous prosthesis implantation, and both procedures, in Brazil and in its regions.

Region	N. of procedures	%				
0	Trabeculectomy					
Northern	112	0.7				
Northeastern	4,066	25.46				
Southeastern	7,655	47.93				
Southern	2,630	16.47				
Central-Western	1,507	9.44				
Brazil	15,970	100				
	Antiglaucomatous					
prosthesis implantation						
Northern	34	1.20				
Northeastern	971	34.41				
Southeastern	1,275	45.18				
Southern	304	10.77				
Central-Western	238	8.43				
Brazil	2,822	100				
	Both					
	procedures					
Northern	146	0.78				
Northeastern	5,037	26.80				
Southeastern	8,930	47.52				
Southern	2,934	15.61				
Central-Western	1,745	9.29				
Brazil	18,792	100				

Source: Tabulation and calculations carried out by the authors

Table 3

Association between rates recorded for Trabeculectomy, Antiglaucomatous Prosthesis Implantation and those recorded for both procedures, and US dollar price or Primary Care coverage, in Brazil and in its regions

Region	Dollar (β)	P-value	PC	P-value			
			coverage				
Trabeculectomy							
Northern	8.761	0.201	0.354	0.328			
Northeastern	0.793	0.376	0.022	0.384			
Southeastern	1.018	0.133	0.046	0.083			
Southern	1.015	0.126	0.044	0.070			
Central-Western	1.103	0.007*	0.013	0.315			
Brazil	1.202	0.132	0.045	0.089			
Antiglaucomatous Prosthesis Implantation							
Northern	-3.732	0.857	0.340	0.744			
Northeastern	-2.267	0.531	-0.012	0.908			
Southeastern	-9.303	0.208	-0.351	0.251			
Southern	16.727	0.006*	0.643	0.009*			
Central-Western	-6.781	0.281	-0.092	0.514			
Brazil	-5.721	0.459	-0.161	0.554			
Both procedures							
Northern	6.61	0.299	0.247	0.459			
Northeastern	0.595	0.499	0.020	0.425			
Southeastern	0.93	0.183	0.042	0.121			
Southern	0.998	0.103	0.043	0.056			
Central-Western	1.105	0.012*	0.012	0.335			
Brazil	1,108	0,173	0,042	0,118			

Source: Tabulation and calculations carried out by the authors. \* < 0.05: Statistically significant



Figure 1: Mean annual variation in the number of surgical procedures performed per evaluated triennium

of 1.7%, whereas the second triennium (2011-2013) recorded mean annual variation of -7%. With respect to the number of procedures performed in equivalent periods in the present study, the first triennium (2013-2015) presented mean annual variation of 1.8%, and the second triennium (2016-2018) recorded mean annual variation of 19%.

# DISCUSSION

Glaucoma type, its prognosis and prevalence rates can change depending on the investigated population. African-descendant individuals are the most prevalent among primary open-angle glaucoma patients. They present the most severe cases<sup>(27)</sup>, whereas primary closed-angle glaucoma is more prevalent among Chinese and Eskimo individuals.<sup>(28)</sup>

The population investigated in the present study comprises glaucoma patients subjected to invasive procedures often performed at advanced-stage and refractory glaucoma cases.<sup>(19)</sup> Most patients (32.57%) declared to be white, similar to a study conducted in Brazil, according to which, 74.5% of patients with glaucoma declared themselves white. Such a finding explains the higher surgical rate recorded for the total number of procedures carried out in white individuals, despite the fact that Africandescendants are the ones proportionally presenting the most severe cases. In addition, 37.36% of hospitalized patients did not present race/color information, likely due to poor filling of this yet neglected variable.<sup>(29,30)</sup> According to epidemiological studies, values higher than 30% are classified as poor filling.<sup>(31,32)</sup>

It is essential emphasizing that trabeculectomy and tube-shunt surgery represented the surgical therapeutic options provided by SUS among all interventional procedures performed in the investigated period. They were the only notifiable forms of intervention, since MIGSs are not covered by the Brazilian public health system, although they are lesser invasive and lead to lesser complications.<sup>(20)</sup>

Based on the analysis of the number of surgical procedures performed in the same triennial periods in the past, it was possible seeing that the first triennium (2009-2011) recorded mean annual variation of 1.7%, whereas the second triennium (2011-2013) presented mean variation of -7%. As for the herein investigated period, the first triennium (2013-2015) recorded mean annual variation of 1.8%, whereas the second triennium (2016-2018) presented mean annual variation of 19% – this number was notably higher than that recorded for other periods evaluated under the same circumstances.

Most surgical procedures were performed in the Southeastern and Northeastern regions, which are the most populous regions in the country. <sup>(33)</sup> These regions present the largest absolute number of glaucoma patients and, consequently, the largest number of conducted procedures. Despite the large number of primary care institutions in these regions, <sup>(34)</sup> there was no association between the absolute number of institutions and variation in the number of procedures performed within the investigated period, different from outcomes recorded for the Southern region, where these two variables presented positive association.

Unlike the expected, the Southern region presented increased number of tube-shunt procedures, despite a certain time when this procedure represented greater burden, since its cost increased from R\$ 499.20 (in 2013) to R\$ 873.61 (in 2018). This period-of-time corresponded to the appreciation of the US dollar against the Brazilian Real <sup>(25)</sup> – US dollar price increased by 57% in this time. <sup>(24)</sup> The Southern region has shown increased number of tube-shunt surgeries, whereas the Central-Western region showed increased number of trabeculectomies. Thus, currency price variations did not overall affect the number of medical procedures performed in Brazil, since they increased in the Southern and Central-Western regions.

It is consensus that the clinical treatment applied to glaucoma cases is effective, as evidenced by the Early Manifest Glaucoma Trial; <sup>(35)</sup> however, despite the mean reduction by 25% in intraocular pressure, disease-progression rate reached 60% in treated patients, and this finding shows that the clinical treatment helps, but not enough. Such facts further corroborate the current trend observed among Glaucomatologists to perform interventional procedures, to the detriment of exclusively clinical treatments with poor therapeutic adherence, <sup>(36,37)</sup> in order to enable greater intraocular pressure control, to reduce eye-drop use and, consequently, to improve patients' quality of life.

According to these Glaucomatologists "Intervention in Glaucoma cases is more of a proactive than reactive procedure based on advanced diagnostic methods to actively determine patients at high risk, to be more aggressive in the adopted treatment and to early intervene in disease process." <sup>(38)</sup>

When it comes to SUS, the interventionist trend could be represented by increased number of available procedures, such as trabeculectomy and tube-shunt surgery. These therapies were originally recommended for advanced and/or refractory glaucoma cases; they can be used as early intervention alternative in the Brazilian public health system.

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