

THE PSYCHOSOCIAL AND ECONOMIC BURDEN OF GENITAL WARTS AMONG WOMEN ASSISTED IN SIX SEXUAL AND REPRODUCTIVE HEALTH CLINICS IN BRAZIL

*A CARGA PSICOSSOCIAL E ECONÔMICA DE VERRUGAS GENITAIS EM MULHERES
ATENDIDAS EM SEIS CLÍNICAS DE SAÚDE SEXUAL E REPRODUTIVA NO BRASIL*

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ABSTRACT

Introduction: World Health Organization estimates that 291 million women worldwide will have a human papillomavirus infection. Treatment for genital warts brings discomfort and may be stressful. **Objective:** The objectives are to estimate the psychological burden of genital warts and to estimate its economic burden in six reproductive health clinics in Brazil. **Methods:** Women visiting BEMFAM's clinics from January 2012 until March 2013 filled a self-administered questionnaire based on psychometric scale. The economic burden was measured with a retrospective study of medical chart review of patients assisted from January 2009 to December 2010. **Results:** A total of 122 individuals filled the psychosocial questionnaire. Women with normal Pap smear presented lower scores of worries and concerns about gynecological health than women with cervical intraepithelial neoplasia (CIN) or GW and higher scores of satisfaction with sexual life than women with CIN or GW. Feelings of anxiety and surprise with the last exam were higher in GW group than for normal Pap smear and CIN groups. Each GW episode lasted on average 132 days, had 6 medical visits and costs US\$ 139. **Conclusion:** The economic burden of GW is closely related to psychosocial burden, and the use of health services after a GW episode should be considered in future research. The study of indirect costs is important, considering the number of visits per episode of GW. Additional studies are needed and can help in the advocacy efforts for a comprehensive prevention programs in Brazil.

Keywords: reproductive health, health and costs, genital warts

RESUMO

Introdução: A Organização Mundial de Saúde estima que 291 milhões de mulheres serão infectadas pelo Papilomavírus Humano. O tratamento das verrugas genitais pode ser desconfortável e estressante. **Objetivo:** Estimar a carga psicossocial das verrugas genitais (VG); e estimar a carga econômica das verrugas genitais entre mulheres atendidas em seis clínicas de saúde reprodutiva. **Métodos:** Voluntárias atendidas nas Clínicas da BEMFAM entre 2010 e 2013 preencheram um questionário baseado na escala psicométrica. A carga econômica foi medida através da análise de prontuários de pacientes atendidas entre 2009 e 2010. **Resultados:** O questionário psicossocial foi preenchido por 122 sujeitos. Mulheres com Papanicolaou normal apresentaram menores índices de preocupação quanto à saúde ginecológica e maiores índices de satisfação com a vida sexual do que mulheres com neoplasia intraepitelial (CIN) ou VG. Sentimentos de ansiedade e surpresa com o resultado dos exames foram mais observados entre mulheres com verrugas genitais do que nas com Papanicolaou normal ou CIN. Em média, cada episódio de verruga genital durou 132 dias, demandou seis visitas médicas, e custou US\$ 139. **Conclusão:** Houve relação entre a carga econômica e a carga psicossocial das VG. O maior uso de serviços de saúde após um episódio de verruga genital deve ser analisado em estudos sobre a carga econômica das VG. O presente estudo reforça a importância da análise dos custos indiretos, considerando o número de visitas por episódio de VG. Estudos adicionais podem fortalecer os esforços para programas abrangentes de prevenção no Brasil.

Palavras-chave: saúde reprodutiva, saúde e custos, verrugas genitais

INTRODUCTION

The World Health Organization estimates that 291 million women worldwide will have a human papillomavirus (HPV) infection at any given point in their lifetime⁽¹⁾. Cervical cancer is related to oncogenic types of HPV infection and constitutes a public health issue in Brazil. According to the Brazilian National Cancer Institute 15,590 new cases and a rate of 15,33 cases per 100,000 women are estimated for 2014⁽²⁾.

Although cervical cancer is the most important public health issue related to HPV infection in women, genital warts (GW), a benign condition related to non oncogenic HPV subtypes, cannot be neglected. In 2008, the Brazilian Ministry of Health published a study on sexually transmitted infections (STI) prevalence in selected populations (pregnant women, men working in industry and people seeking care in STI clinics) in five regions of the country⁽³⁾. Genital warts were diagnosed in 5.7% of pregnant women, and 6.5% reported previous episodes. Among women who seek STI clinics, 21% had a GW diagnosis, and 25% reported previous episodes.

Genital warts usually cause stress to the affected individuals. The treatment options bring some kind of discomfort, such as burning sensation and pain. Besides, as a sexually transmitted infection, it may be associated with feelings of shame, anxiety and problems in the relationship with the partner.

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Zhu *et al.*⁽⁴⁾ developed a psychometric scale to assess the psychological burden of HPV. The self-administered questionnaire consists of 29 questions designed to capture a wide range of psychosocial consequences of HPV disease, including both cervical cancer precursors and genital warts. The results were sensitive to differences in the psychosocial impact of various HPV-related diseases.

There are studies about costs of GW treatment in many countries; some of them consider only direct costs^(5,6) and others include indirect costs such as sick leave⁽⁷⁻⁹⁾. Considering the importance of HPV and related diseases in Brazil and the lack of studies about both the psychosocial and the economic burden of these diseases, *Bem Estar Familiar no Brasil* (BEMFAM – Family Wellbeing in Brazil) carried out a study to measure the psychosocial and economic burden of genital warts among two samples of women attending its six reproductive health clinics. BEMFAM is a Brazilian non-governmental organization that provides sexual and reproductive health (SRH) services and technical support to local governments.

OBJECTIVE

There are two objectives in this paper: (i) to estimate the psychological burden of genital warts (GW); and (ii) to estimate the economic burden of GW in six reproductive health clinics in Brazil.

METHODS

The study design comprises two objectives and groups of women assisted in the six BEMFAM's SRH clinics in the Brazilian Northeast States of Maranhão, Paraíba, Rio Grande do Norte, Pernambuco, Ceará and the Southeast State of Rio de Janeiro. All the clinics are located in urban areas of the State capital cities, provide outpatient care and assist both individuals who pay out-of-pocket or with private health plans. All the individuals were assisted by gynecologists. The psychosocial burden was measured by a self-administered questionnaire at the time of the visit and the economic burden was measured with a retrospective study of medical chart review analysis.

Self-administered questionnaire

Women who visited the six BEMFAM's clinics from January 31st, 2012 until March 1st, 2013 were invited to participate in the study. Inclusion criteria were women aged 18–45 years, who had a Pap smear in the preceding 90 days or were diagnosed with genital warts during physical examination, in good health. Women who self-reported to be positive for Human Immunodeficiency Virus (HIV) serology, undergoing antiretroviral treatment, illiterate or pregnant were excluded.

Women who accepted to be a volunteer signed an informed consent and answered a socio-demographic questionnaire and a psychometric scale test applied by nurses. Both questionnaires were pretested through in-depth interviews with clients, to evaluate ease of understanding and adequacy of translations.

All volunteers received written information and an educational counseling session about prevention and treatment of HPV after filling the self-administered questionnaire. Women belonging to the groups with cervical intraepithelial neoplasia (CIN) 1 and CIN 2-3, also had a colposcopy and/or biopsy free-of-charge.

Medical chart review

In order to identify patients with GW, medical records of women who consulted from January 2009 to December 2010 and had undergone one of the procedures that could be related to GW treatment were analyzed. The procedures were provider-applied modalities to treat vulvovaginal or anal lesions. Criteria for enrollment in the study comprise women aged 18 to 45 years, with a GW diagnosis in the preceding twelve months and in good health. Pregnant women, those infected with HIV, women with only vestibular micropapillomatosis and with abnormal Pap smear were excluded.

The individuals were classified as (1) newly diagnosed (never having been diagnosed before with GW); (2) recurrent (those who had previous episodes of GW but who had been free of lesions for at least 12 months); and (3) resistant (those who had previous episodes of GW that remained despite treatment).

All the visits, exams and treatment information were collected by nurses using a checklist form and then sent to the medical department for data review. Cost analysis was carried out considering treatment costs from the payer's perspective. Exams not specific to GW, but performed during the episodes to investigate other HPV related lesions, such as Pap smear and colposcopy were included. Indirect costs were not included. Unit costs for visits and treatments were used to estimate the cost per episode of care, which is defined as the period between the first and the last clinic visit for GW treatment. Costs were based on BEMFAM and private health plans prices in 2013. All costs were converted to US dollars at an exchange rate of 1 US\$ = R\$ 2.3 (Brazilian reais).

Sample size and statistical analysis

A target sample size of 120 cases for the psychological scale and 100 cases for the medical records review was set. The study aimed at recruiting 30 cases each in the eligibility groups of normal Pap test, CIN 1, 2-3 and GW, for the sample on psychological burden. Due to the low number of cases CIN 1 and 2-3 were regrouped in one single group for analysis. Also, data from all clinical centers was regrouped in one dataset due to small numbers. No systematic differences on samples recruited in the different centers were expected.

RESULTS

Sample characteristics are displayed in **Table 1**.

Mean age was similar for both samples, with a slightly younger population for the sample under medical record review (25.8 *versus* 27.6). Most of the sample enrolled for the psychometric part of the study was married, earning a family income of less than US 11 a day, with one living children and was revisiting BEMFAM clinics. They used modern contraception in larger proportions than women under medical record review (82.8 *versus* 75%). Prevalent methods among the first were pills (43%) and condoms (34%) against pill (35%), condom (29%) and sterilizations (13%), for the second. Fifty three cases were enrolled from the normal Pap smear group, 29 with CIN 1, 6 cases with CIN 2 or 3 and 34 cases with GW. For the psychometric scales, cases with CIN 1, 2 and 3 were regrouped,

Table 1 – Characteristics of participants in the study.

Sample Characteristics	Self-administered questionnaire (n=122)
Mean age at enrollment, years (*) (95%CI)	27.6 (24.3–30.2)
Visit Type (%)	
First	13.4
Revisit	86.6
Mean number of leaving children (min–max)	0.85 (0–9)
Average monthly family income US\$ (%)	
<234	11.8
235–335	59.8
336–480	19.6
480–723	8.8
% married or in stable union	90.2
Eligibility groups	
Normal Pap smear	53
CIN 1	29
CIN 2, 3	6
Genital Warts	34
Contraceptive use (%)	82.8
	Medical records (n=102)
Mean age at enrollment, years (*) (95%CI)	25.8 (24.5–27.2)
Mean age at first intercourse (95%CI)	17.8 (17.0–18.6)
Contraceptive use (%)	75.0
First or recurrent episode (%)	
First	90.2
Recurrent	2.0
Resistant	7.8
Mean duration of episodes, in days (95%CI)	132.2 (96.9–76.0)
Mean number of normal deliveries (min–max)	0.18 (0–3)
Mean number of caesarean sections (min–max)	0.16 (0–2)
Mean number of abortions (min–max)	0.22 (0–5)
Payment (%)	
Out-of-pocket	95.1
Private insurance	4.9

(*) Age at first genital warts diagnostic for medical records.

totaling 35 cases. The sample for medical review had the first intercourse at 17.8 years old in average, were experiencing their first GW episode for 90.2% of the total sample, with 2.0% being recurrent and 7.8% resistant cases. In average, women from the medical record sample had 0.18 normal deliveries, 0.16 cesarean sections and 0.22 abortions. Treatment payment with money out-of-pocket represented 95.1%.

The psychometric scale met with asymmetric results, with skewness above 1 for several item scales, as depicted in **Chart 1**. Scale items with skewness above the threshold of 1 were not retained for analysis. Overall, there were very few missing cases to observation.

Four factors were regrouped during exploratory factor analysis (varimax rotation) and are displayed in **Table 2**.

Women with normal Pap smear presented lower scores of worries and concerns about their gynecological health (fear of test results, implications for fertility, fear of no cure for abnormal Pap smear or for cervical cancer, risks of infecting the partner or herself during sexual relations) than the group with CIN or GW. However, there was no significant difference in worries between the groups with CIN and GW. Scores of satisfaction with sexual life (feeling their bodies sexually attractive, satisfied with their sex life, relaxed after

last gynecological exam and not disgusted with tests or exams) were also higher for women with normal Pap smear than for the other two groups. Again, differences in feelings about sexual life were not statistically different for women with CIN and GW. Feelings of anxiety and surprise (felt anxious or surprised with last exam or were concerned about GW) were higher for GW group than for the CIN and normal Pap smear group, in that order. All differences for the anxiety and surprise factor were statistically significant. Finally, there were no statistically significant differences in the factor of distress and shame (feeling ashamed, not in control of everyday life or of own health) among the groups.

Medical records analysis showed that each GW episode last in average 132 days (Table 1) and cost US\$ 139 with private health plan and US\$ 105 with BEMFAM's clinics subsidized tariffs. Cost figures per episode of GW, number of encounters (visits) and cost per procedure are depicted in **Table 3**. Regarding the medical procedures, in 95 episodes, the provider applied trichloroacetic acid as the only treatment. It was also associated with electrosurgery in one episode, with excision and imiquimod in six episodes each. Excision was the only treatment in four episodes. Other procedures described were consultations, Pap smear and colposcopy.

Chart 1 – Scale properties and factor loads.

Scale Items	Factor Loads				n		Mean	Standard Deviation	Skewness
	Worries/ Concerns	Sexual life/ Discomfort	Anxiety/ surprise	Distress/ shame	Valid	Missing			
1. When I think about my recent gynecological exam or test results, I feel good about myself.			-0.588		122	0	5.40	3.461	-0.258
2. When I think about my recent gynecological exam or test results, I feel anxious.			0.814		122	0	5.59	3.440	-0.195
3. I feel my recent gynecological test results were unexpected.			0.537		122	0	4.61	3.928	0.078
4. When I think about my recent gynecological exam or test results, I feel in control of my health.				-0.782	122	0	6.30	3.115	-0.651
5. When I think about my recent gynecological exam or test results, I feel depressed.					122	0	2.45	3.278	1.217
6. After my recent gynecological exam or test result, I feel I can concentrate as well as usual on everyday matters.				-0.631	122	0	6.41	3.055	-0.545
7. When I think about my recent gynecological exam or test results, I feel something is seriously wrong with me.					122	0	2.23	3.109	1.242
8. When I think about my recent gynecological exam or test results, I feel angry.					122	0	1.62	3.065	2.043
9. After my recent gynecological exam or test result, I feel confident my partner will accept me.					121	1	7.19	3.477	-1.188
10. When I think about my recent gynecological exam or test results, I feel my body is sexually attractive.		-0.582			122	0	4.32	3.283	0.045
11. When I think about my recent gynecological exam or test results, I feel ashamed.				0.537	121	1	3.02	3.465	0.906
12. I feel concerned about having genital warts.			0.638		119	3	3.74	4.420	0.490
13. I am worried there are no treatments to cure genital warts.					119	3	3.44	4.096	0.617
14. After my recent gynecology exam or test result, I feel optimistic about my future gynecological health.					122	0	7.50	2.806	-1.012
15. I am worried about having abnormal Pap test results.	0.606				122	0	3.67	3.915	0.418
16. I am worried that there is no cure for what causes an abnormal Pap test.	0.789				122	0	3.95	4.045	0.316
17. I am worried about my fertility because of my recent gynecological health or test results.	0.546				122	0	3.43	3.983	0.577
18. I am concerned I will get cervical cancer in the future.	0.725				122	0	5.83	3.893	-0.430
19. I am worried that there are no treatments to cure cervical cancer.	0.821				122	0	5.84	4.066	-0.396
20. I am worried about having pain during future gynecologist visits.	0.637				122	0	4.26	3.724	0.280
21. After my recent gynecologist exam or test results, I am worried that having sex with my partner may give him/her an infection.	0.607				121	1	4.29	4.226	0.236
22. After my recent gynecologist exam or test results, I am worried that having sex with my partner may give me an infection.	0.704				120	2	4.58	3.972	0.113
23. I felt disgusted by my recent gynecological exam or test results.		0.536			121	1	2.97	3.717	0.887
24. After my recent gynecological exam or test results, I am having less sex.					122	0	2.61	3.491	1.038
25. After my recent gynecological exam or test results, I feel satisfied with my sex life.		-0.755			122	0	5.69	3.700	-0.261
26. After my recent gynecological exam or test results, the quality of my sleep has decreased.					122	0	1.89	3.097	1.465
27. I felt relaxed after my recent gynecological exam.		-0.627			122	0	5.83	3.839	-0.390
28. I felt my recent gynecological procedures were embarrassing.					122	0	1.98	3.033	1.522
29. I felt the medical procedures at my recent gynecological exam were uncomfortable.					122	0	1.57	2.895	1.788

Table 2 – Psychological burden exploratory factors.

Psychological Burdens	Factor Numbers (*)	Normal Pap test	CIN 1, 2–3	Genital Warts
Worries/Concerns	15,16,17,18,19,20,21,22	1.94 (1.12 – 2.75)*	6.58 (5.27 – 7.86)	6.65 (5.45 – 7.85)
Sexual life/Comfort	10, 23, 25, 27	5.56 (4.87 – 6.33)*	4.01 (2.86 – 5.16)	4.21 (2.98 – 5.45)
Anxiety/surprise	2, 3, 12	2.35 (1.55 – 3.16)*	5.92 (4.59 – 7.26)*	7.15 (6.10 – 8.19)
Distress/shame	4, 6, 11	5.52 (4.91 – 6.13)*	4.79 (3.66 – 5.92)	5.38 (4.27 – 6.50)

(*) Significantly different at 95% confidence interval (bootstrap)

Table 3 – Costs of genital warts treatment at BEMFAM clinics.

Type of Payment	Cost per episode (n = 102)	Number of visits per episode	Cost per procedure (n = 613)
Private Health Plans			
Mean	\$ 139.45	6.13	\$ 23.31
Standard Deviation	\$ 62.76	2.77	\$ 4.55
Out-of-Pocket			
Mean	\$ 105.02	6.13	\$ 17.85
Standard Deviation	\$ 46.82	2.77	\$ 5.15

DISCUSSION

The results of this research are consistent with findings from other studies showing a high psychological and economic burden of the disease. However, the average number of visits per episode is higher than reported elsewhere⁽⁸⁻¹²⁾. According to the analysis of medical records, home treatment with imiquimod was also prescribed less often than reported by other studies⁽⁷⁻¹¹⁾. Most cases of GW were treated with provider-applied trichloroacetic acid that is cheaper than patient applied imiquimod, which is neither provided by public sector nor by private health plans. This probably explains the higher number of mean visits in our study.

Average costs per episode (US\$ 105) might also appear low when compared to other countries but it is not when compared with an average monthly income for 91.2% of women enrolled in our study, that is under US\$ 480. For this population, about one-week wages is necessary to provide for treatment, indirect and social costs not included.

Woodhall *et al.*⁽¹³⁾ wrote that concerns over future recurrence and transmission to new partners could impair the quality of life of subjects after completion of an episode. In our study the results from the psychosocial scale suggest that the psychological burden of GW is at least as distressful and heavy as for the CIN diagnosis and much heavier than for the normal Pap smear group. All the negative feelings associated to GW may lead to sexual dysfunction, low self-esteem, risky behavior and the need to use additional health services, increasing the GW related costs.

Those results prompt for practical implications and future research directions. Free access to public healthcare is a constitutional right for all Brazilian citizens. Nevertheless, there are 50.7 million users of private health plans in the country⁽¹⁴⁾, which means that almost 25% of the population is resorting to complementary or substitute sources of healthcare. Low income citizens constitute the majority of users of public primary health care services. Those who cannot afford a private health plan but prefer private assistance pay for low fee private health services, as the clients enrolled in this study did.

HPV is the most common viral reproductive tract infection. Primary prevention includes vaccination, sexuality education and condom promotion⁽¹⁵⁾. According to the International Federation of Gynecology and Obstetrics⁽¹⁶⁾, all randomized controlled clinical trials provide evidence of a safety profile for the two vaccines against HPV: the bivalent Cervarix (GlaxoSmithKline) and the quadrivalent Gardasil (Merck, Co., Inc.). In Brazil both vaccines are available in the private market and the Ministry of Health included the quadrivalent vaccine in the national vaccination programme since March 2014, for 11–13 year-old girls.

A national study about knowledge, attitudes and practice in the Brazilian population⁽¹⁷⁾, revealed that 26.8% of those who reported at least one sexual intercourse in the last twelve months had had sexual debut before the age of 15. This national study also revealed that only 24.6% of women had free access to condoms in the past year. A survey on adolescent sexual behavior in a public Brazilian high school showed that at the age of 14, 39% boys and 8.5% girls declared being sexually active⁽¹⁸⁾. Advocacy efforts for the scaling up of the government vaccination program in order to include boys and to expand the age range for the target population of the public vaccination campaigns should be considered. Promoting condom access and use and sexual education cannot be neglected. In addition, the use of imiquimod for treatment should be encouraged and provided through public sector channels. Besides, as the private health plans serve almost 25% of Brazilian population, their contribution to vaccine access should be encouraged.

Despite the relevant results of our study, which shows an excessive psychological and economic burden of GW among the clinics surveyed, there are some limitations to the study that open venues for new research. The main limitations of this study are the analysis of only part of the economic burden of the disease, from the payers' perspective and the fact that the sample is not representative of the country but of BEMFAM's clinics. A comprehensive cost analysis should also include social costs that emerge from the conflict between sexual partners and domestic violence⁽¹⁹⁾. Finally, the asymmetry in the scales prevented us from analyzing different

psychological burdens of the disease due to the non-validation of some scale items in this study. The expansion of the sample for confirmatory factor analysis is also suggested.

CONCLUSION

Our study shows that the economic burden of GW is closely related to psychosocial burden of disease, and health service use after a GW episode should be considered in next studies. The study of indirect costs is also important, considering the mean number of visits per episode of GW. Additional studies about both the psychological and the economic burden of GW are needed and can help the advocacy efforts for a comprehensive primary prevention program in Brazil, with the participation of the private health sector.

Conflict of interest

The study has received funding from Merck Investigator Studies Program.

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