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Repercussions of the Use of Imiquimod in Genital Warts

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ABSTRACT

Introduction: The manifestations of a sexually transmitted infection such as condyloma acuminatum generated by the HPV virus are reflected in the increase in the prevalence curve in women and men.

Objective: To analyze the effectiveness of Imiquimod on anogenital warts in immunocompetent women and men. Methods: The search strategy was made in PubMed, Scielo, LILACS and Google Scholar, Scopus, Trip Database. only 13 articles entered.

Results: Sauder et al, 2003 Imiquimod at 5%, efficacy in women and men 72% and 33% respectively. Baker et al, 2011 efficacy Imiquimod 2.5% 28.3%, Imiquimod 3.75% 36.6%. Trofater et al, 2002 with frequency of administration of 5% Imiquimod 1 time per day, 2 times per day and 3 times per week efficacy of 72%, 63% and 62% respectively. Komericki et al, 2011podophyllotoxin with Imiquimod, podophyllotoxin efficacy 72%, Imiquimod 75%. Aricano et al, 2014 Imiquimod efficacy 69.7%. Gilson et al, 2020 Imiquimod plus vaccine efficacy 56%, Podophyllotoxin plus vaccine 54%, Imiquimod plus placebo50%, podophyllotoxin plus placebo 56%. Garland et al, 2006 Imiquimod efficacy 51.6%. Gollnick et al, 2001 efficacy of Imiquimod at 5% 61.8% 3 times a week and 56.7% once a day. Edwards et al, 1998 efficacy of Imiquimod at 5% 72% women and 33% men at 1% efficacy in women 38% and men 7%.

Conclusions: Imiquimod has been shown to be a drug with good efficacy and safety in the treatment of HPV-related genital warts.

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Introduction

Genital infection by Human Papillomavirus (HPV) reaches clinical manifestations in 1%, with an estimated prevalence of 10 to 20%, with an incidence that has been increasing. 90% of genital warts are related to HPV 6 and 11.The clinical pictures show four forms of genital warts: flat, cauliflower, smooth papular and keratotic. Among the predisposing factors are Human Papillomavirus (HPV) infection, also incorporating local trauma, diabetes and immunosuppression, Treatment depends on the location, extent, size of the lesion and the status of the pregnancy [1-3].

Genital warts are the most common sexually transmitted infection, they mainly affect younger people and are generally caused by HPV genotypes 6 or 11, which classifies them according to the International Council on the Taxonomy of Viruses within the genus Alpha Papillomavirus and are included in the production of condylomas and papillomas in the lower genital tract, anal and larynx. (Chen4 et al 2016). Genital warts after clinical manifestation can increase in size and number or show spontaneous regression, reaching a 30% regression within the first 4 months. However, genital warts can reappear within three months after infection up to after undergoing appropriate treatments [4,5].

Imiquimod, the first of a new class of compounds called immune response modifiers, is a low-modular non-nucleoside heterocyclic amine (imidizoquinolone) with the chemical structure 1-(2-methylpropyl)-IH-imidazole [4,5 -c] quinolin-4-amine. It is approved in the United States as a patient-applied treatment for external genital and perianal warts/condylomata acuminata in adults, but the majority of Imiquimod use has been for off-label infectious and neoplastic indications. Imiquimod has been shown to have antiviral properties and antitumor effects in experimental studies in animal models but not direct antiviral or antitumor activity in vitro [6].

The ability of Imiquimod to achieve an expected effect, due to its effectiveness, its chemical composition C14H16N4 in its different presentations and its application, achieves a specific immune response in genital warts, locally promoting the synthesis of cytokines, mainly interferon alpha, tumor necrosis factor. and various interlukins, enhancing the Th1 type immune response, producing antiviral effects and consequently the disappearance of lesions acquired by unprotected sexual transmission.

The objective of this work was to analyze the effectiveness of Imiquimod in anogenital warts, whose study addresses the

effectiveness of this topical immunomodulator in the treatment applied to immunocompetent women and men.

Methods

Design and Study Area

The starting point of this study is generated in the Isidro Ayora Obstetric Gynecological Hospital located in the Metropolitan District of Quito, capital of Ecuador, a globalized city, declared a World Heritage Site by UNESCO, subtropical climate, divided into three zones: north, center and south, to specify the Hospital is located in the historic center of the city of Quito.

Thus, this research begins in the clinical experience of the outpatient clinic of this Hospital, in the area of colposcopy and pathology of the lower genital tract, where the question arises of the effectiveness of Imiquimod as a treatment for genital warts, the importance of which study lies in the efficacy, recurrence and collateral effects in condylomatous lesions at the genital level; whose response allows us to formulate criteria under the acronym PICO, generating this study and its theme.

Population Study and Sample Calculation

The search strategy in this study process followed the recommendations of Page et al, 2020 (32). Considering in the first instance the selection of keywords from selected articles within the study.

Medical Subject Headings (MeSH) are used to find related keywords with similar meanings: ("Imiquimod" [MeSH Terms] and "Genital warts" [MeSH Terms] "Condyloma treatment" [MeSH Terms]. Thus, in The database is generated by searching for keywords in the periods from 1998 to 2022. The filter was applied Randomized controlled trial and two 253 articles were only 24 articles. These 24 articles, 11 articles are not in accordance with the topic, subject (As is in the direct part of figure 1.) Beyond this criterion of exclusion 13 articles, not which formats the complete texts and the 13 articles will enter the systematic review.

After all the databases, 13 articles were included in the systematic review (Figure 1).

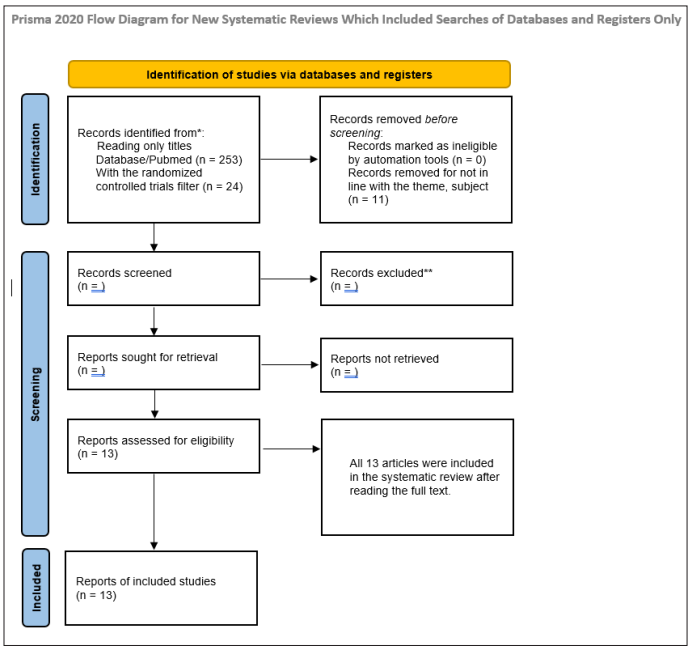
PRISMA Recommendation

According to Page MJ, Mckenzie J in its Guide to Writing a Systematic Review article is described in the concept of P.I.C.O. therefore in this investigation the description P. I.C.O. is the following:P. Definition of the patient. Immunocompetent women and men with genital warts. I. Intervention to analyze Women and men who were treated with Imiquimod [7].

C. Comparison of interventions. Women and men who were treated with Imiquimod and women and men who were treated with another topical treatment. O. Outcomes (results obtained) Efficacy result of Imiquimod.

Results

The database includes keywords described in materials and methods where 129 articles are found, of which no duplicates were obtained, and 116 articles were discarded due to exclusion criteria. After reading the titles and summaries, 116 articles were excluded. for the following: 97 articles did not correspond to the topic, 2 articles in another language and 26 articles with other treatments not included in the inclusion criteria, so the result of 7 articles that will be included in the study is reached (Figure 1).

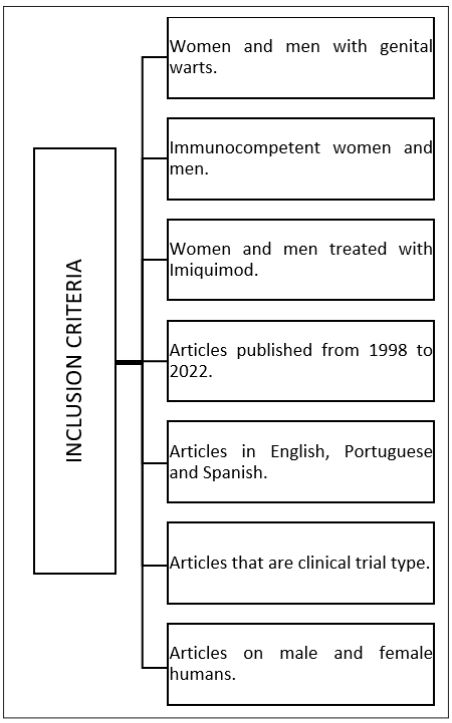


*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Table 1 and table 2 contains information on the studies selected in this systematic review.

Table 1: Inclusion and Exclusion Criteria



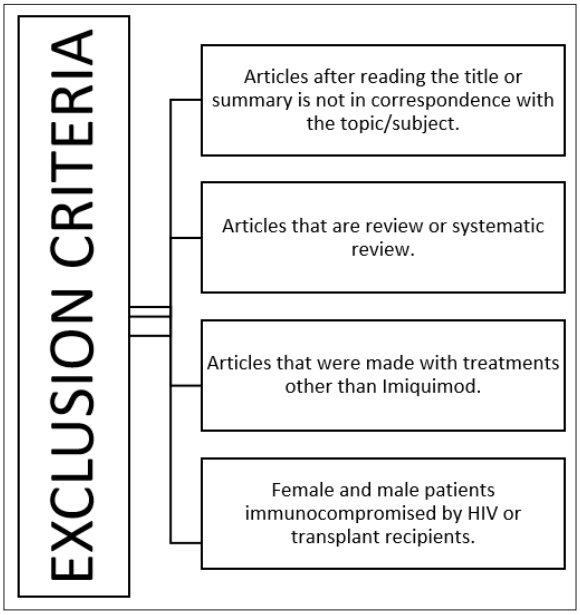


Table 2: Articles Found by Author, Year, Type of Study, Country, Sample Size, Type of Treatment, Efficacy, Recurrence, Adverse Reactions

Author	Year	Type of Study	Country	Show Size	Intervention	Effectiveness
Sauder, et al.	2002	ECA	USA Canada	86 patients	Compare Imiquimod to Placebo 3 times a week until the wart is gone or for up to 16 weeks.	**Elimination Rate by Intent to Treat** **Complete elimination patients treated with** 5% Imiquimod 50% (54/109) Placebo 11% (11/100) p < 0.0001 **Complete elimination by sex** **Women** Imiquimod at 5% 72% Placebo 20% **Men** Imiquimod 5% 33% Placebo 5% **Efficacy per wart area** < 34mm ² Imiquimod 5% 59% Placebo 13% 34 < 75mm ² Imiquimod 5% 48% Placebo 18% 75mm 2 -162 Imiquimod 5% 40% Placebo 14% >162mm ² Imiquimod 5% 50% Placebo 0% **Efficacy by duration of wart outbreak** ≤ 6 meses Imiquimod 5% 58% Placebo 17% > 6 meses Imiquimod 5% 40% Placebo 4 %

Baker, et al.	2011	ECA	USA	534 patients women	Compare Imiquimod 2.5% Imiquimod 3.75% with Placebo applied once a day until complete elimination or a maximum of 8 weeks.	**Complete Intent-to-Treat Clearance** Placebo 14.2% Imiquimod 2.5%: 28.3% Imiquimod 3.75%: 36.6% **Complete clarification by Protocol** Placebo 16.1% I Imiquimod 2.5%: 35.1% Imiquimod 3.75%: 43.1% **Partial clearance greater than or equal to 75% per Protocol** Placebo 18.4% Imiquimod 2.5%: 45.7% Imiquimod 3.75%: 56.2% **Change in wart count Per Protocol** Placebo -10.7% Imiquimod 2.5%: -50.9% Imiquimod 3.75%: 63.5% **Anatomic site-specific clearance rates, by protocol population,** **Vulvar:** Placebo 14/51 (27.5%) Imiquimod 2.5%: 42/98 (42.9%) Imiquimod 3.75%: 53/104 (51.0%) **Inguinal:** Placebo 2/9 (22,2 %) Imiquimod 2,5%: 4/18 (22,2%) Imiquimod 3,75%: 9/20 (45,0%) **Perineal:** Placebo 11/43 (25,6 %) Imiquimod 2,5%: 36/68 (52,9%) Imiquimod 3,75%: 48/74 (64,9%) **Perianal:** Placebo 10/40 (25.0%) Imiquimod 2.5%: 34/69 (49.3%) Imiquimod 3.75%: 51/65 (78.5%) Change in wart count from baseline, mean percentage (standard deviation) **Vulvar:** Placebo −23.8 Imiquimod 2.5%: −52.3 Imiquimod 3.75%: −56.8 **Inguinal:** Placebo −27.2 Imiquimod 2.5%: −14.4 Imiquimod 3.75%: −49.3 Perineal: Placebo −21.3 Imiquimod 2.5%: −61.8 Imiquimod 3.75%: −74.6 **Complete elimination and entered the 12-week follow-up phase, complete elimination remained at** Placebo 9/9 (100.0%), Imiquimod 2.5% 32/53 (60.4%) and Imiquimod 3.75% 47/72 (65.3%)
Trofatter, et al.	2002	Phase II open-label study	USA Canada	90 patients	Imiquimod 5% applied twice a day, once a day or three times a week, until complete resolution or up to 16 weeks	**Elimination 100% removal** Twice a day (n 32) 20 (63%9) Once a day (n 32) 23 (72%) Three times a week 16 (62%) **Elimination greater than 50%** Twice a day (n 32) 29 (91%) Once a day (n 32) 30 (94%) Three times a week (n 26) 22 (85%)
Komericki, et al.	2011	Randomized and open trial	Austria	51 patients	Imiquimod 3 times a week until the warts are completely gone, or for a maximum period of 16 weeks. Podophyllotoxin was used 2 times for 3 consecutive days per week until the warts completely disappeared, or for a maximum period of 4 weeks.	**Complete Clearance** Podophyllotoxin 0.5% (n 18 72%) [95% CI], 52%–86%) Imiquimod 5% (n 15 75%) (95% CI, 53%–89%) **No Clarification** Podophyllotoxin 0.5% (n 7 28%) [95% CI, 14%–48%) Imiquimod 5% (n 5 25% [95% CI], 11%–47%)

Aricano, et al.	2004	Randomized, double-blind trial Placebo controlled study	Turquia	43 patients	Imiquimod 5% 3 times a week for 12 weeks compared to Placebo	Distribution of clinical improvement according to sex and location of the disease at the end of the study Group I: study group: Women Vulva 0—10% (0) 11—50% (0) 51—99% (0) Complete (5) Perianal área 0—10% (0) 11—50% (0) 51—99% (0) Complete (5) Vulva and perianal área 0—10% (0) 11—50% (0) 51—99% (0) Complete (1) Men Perineal área 0—10% (0) 1—50% (0) 51—99% (0) Complete (7) Pubis 0—10% (0) 11—50% (0) 51—99% (2) Complete (1) Penis 0—10% (0) 11—50% 1) 51—99% (3) Complete (3) Penis and scrotum 0—10% (0) 11—50% (0) 51—99% (1) Complete (0) Penis, scrotum and perianal área 0—10% (0) 11—50% (0) 51—99% (1) Complete (0) Pubes and pênis 0—10% (0) 11—50% (0) 51—99% (1) Complete (1) Scrotum, penis and púbis 0—10% (0) 11—50% (0) 51—99% (1) Complete (0) Group II: control group Women Vulva 0—10% (0) 11—50% (ā0) 51—99% (1)

						Complete (0) Perianal área 0—10% (1) 11—50% (0) 51—99% (0) Complete (0) Men Perianal área 0—10% (1) 11—50% (0) 51—99% (0) Complete (0) Pubis 0—10% (2) 11—50% (0) 51—99% (0) Complete (0) Penis 0—10% (1) 11—50% (0) 51—99% (0) Complete (0) Penis, scrotum and perianal area 0—10% (1) 11—50% (0) 51—99% (0) Complete (0) Pubes and penis 0—10% (1) 11—50% (0) 51—99% (0) Complete (1) Scrotum, penis and púbis 0—10% (1) 11—50% (0) 51—99% (0) Complete (0) Study group 1 patient 3% improvement less than 50% 9 patients (27.3%) showed improvement of 50-90% 23 patients (69.7%) were completely cured, all women and 54.5% of men. By sex, women presented an earlier improvement than men (p=0.007) Control group In 1 patient (10%) the improvement was 50 to 90% 1 patient (10%) had complete clearance. The remaining 80% of patients did not show improvement. Recoveries between weeks 6 and 12 In both sexes the response to the treatment applied to the perianal area was better and faster. (p<0.001)
Gilson, et al.	2020	ECA	London, United Kingdom	503 patients	Imiquimod plus vaccine Podophyllotoxin plus vaccine Imiquimod plus placebo Podophyllotoxin plus Placebo	Imiquimod plus Vaccine 56% Imiquimod plus Placebo 54% Podophyllotoxin plus Vaccine 70% Podophyllotoxin plus Placebo 56%
Garland, et al.	2006	Open phase II pilot trial, Randomized, Multicentric	Australia	120 patients	Imiquimod 5% 3 times a week, assessment at 4 weeks, 8 weeks, 12 weeks, 16 weeks	Complete Clearance 4 weeks (n=30) 12 (40,078.94%) 8 weeks (n=31) 15 (48,478.98%) 12 weeks (n=28) 11 (39,379.23%) 16 weeks (n=31) 16 (51,678.98%) p: 0.724 No clarification 4 weeks (n=30) 5 (17.0%) 8 weeks (n=31) 10 (32.0%) 12 weeks (n=28) 9 (32.0%) 16 weeks (n=31) 7 (23.0%)

Gollnick, et al.	2001	Open phase II pilot trial, Randomized, Multicentric	USA Canada	64 men 34 received 3 times a week 30 received 1 time per day. For 16 weeks	Imiquimod al 5% en hombres no circuncidados 3 veces por semana, 1 vez por día por 16 semanas	Complete removal of warts At week 16, 21/34 patients (61.8%) 3 times a week At week 16, 17/30 patients (56.7%) once a day Complete elimination Imiquimod at 5% 3 times a week, at week 16 21/34 patients (61.8%) Imiquimod 5% once a day a week 16 17/30 patients (56.7%) Average clearance time Imiquimod 5% once a day for 10.3 weeks. Imiquimod 5% 3 times a week 12.7 weeks (95% confidence interval [Cll 9.4-17.0
Rosen, et al.	2015	Two multicenter, randomized studies Double blind, Placebo controlled	USA	447 men Studio 1 225 Study 2 222	Imiquimod 3.75%, Imiquimod 2.5%. Placebo applied 1 time per day until complete elimination or up to 8 weeks. Participants who achieved complete elimination were observed for an additional 12 weeks.	Complete Clearance Study 1 Imiquimod 3.75% (n=183) 12% Imiquimod 2.5% (n= 168) 7.2% Study 2 Imiquimod 3.75% (n=183) 9.1% Imiquimod 2.5% (n= 168) 7.1% Elimination by Intent to Treat Study 1 Imiquimod 3.75% (n=183) 20% Imiquimod 2.5% (n= 168) 13.3% Study 2 Imiquimod 3.75% (n=183) 17% Imiquimod 2.5% (n= 168) 15.3% Rest periods 18% of participants took rest periods Complete removal rates Men who had a rest period Imiquimod 3.75% 26.5% Imiquimod 2.5% 27.3% 75% reduction Study 1 Imiquimod 2.5% (n= 168) 18.1% Imiquimod 3.75% (n=183) 30.5% Study 2 Imiquimod 2.5% (n= 168) 22.4% Imiquimod 3.75% (n=183) 23.9% Median complete removal time Study 1 Imiquimod 3.75% (n=183) 57 days Imiquimod 2.5% (n= 168) 60 days Study 2 Imiquimod 3,75% (n=183) 59 días Imiquimod 2,5% (n= 168) 74 días Placebo Study 1 81 days Study 2 76 days
Edwards, et al.	1998	Randomized, double-blind, controlled comparison placebo	USA	311 total 131 women 180 men	Imiquimod 5% and 1% with placebo Application 3 times a week for 16 weeks or until the warts disappear	Elimination by Intent to Treat Patients who remove initial warts Women Imiquimod 5% Imiquimod 1% Placebo Men Imiquimod 5% Imiquimod 1% Placebo Elimination by Intent to treat: Imiquimod at 5% 50% Imiquimod 1% 21% Placebo 11% p: 0.001 Complete elimination Women 72% Men 33%

Beutner, et al.	1998	Prospective, Double-blind, Placebo-controlled clinical trial	USA Colorado	108 men 51 patients received Imiquimod 57 patients received placebo	Imiquimod 5% 3 times a week for 8 weeks	Intention-to-treat analysis Complete Removal 37% (19 of 51) Patients treated with imiquimod. 0% (0 of 57) Placebo. ($p < 0.001$) Reduction of 80% or more 62% (28 of 45) with Imiquimod 4% (2 of 50) with Placebo ($p < 0.001$) Reduction of 50% or more 76% (34 of 45) with Imiquimod. 8% (4 out of 50) with placebo ($p < 0.001$).
Fife, et al.	2001	Randomized Treatment Trial	USA	110 Men	Imiquimod 5%, for all external warts 3 times a week, 1 time a day, 2 times a day and three times a day	Complete elimination during treatment 16 weeks Imiquimod 3 times a week 35% Imiquimod once a day 28% Imiquimod 2 times a day 24% Imiquimod 3 times a day 27% Median elimination time Imiquimod 3 times a week 10 weeks Imiquimod 1 time per day 9 weeks Imiquimod 2 times a day 7 weeks Imiquimod 3 times a day 10 weeks
Arany, et al.	1999	Randomized, Double-blind, Controlled study with Placebo	USA	12 Men 10 Woman	Imiquimod al 5% comparado con placebo 3 veces por semana por 16 semanas	Eliminación del 75% Imiquimod al 5% 16 100% Placebo 1

Discussion

This research and its processes lead to the main results found in the articles that were included to specify the systematic review, evidencing greater effectiveness of the treatments with the use of Imiquimod compared to other treatments, when applied to the affected area in this case. anogenital warts. Patel et al, 2013, within the risk factors related to the development of genital warts, in several studies it was evident that both genders present diagnoses of genital warts [8].

Uusküla in a cross-sectional study showed that 5 or more sexual partners throughout life is related to having received the diagnosis of anogenital warts, while in another study it was observed that 14 or more sexual partners constitute a risk factor for the development of genital warts (Anneli Uusküla,1), a higher risk of developing anogenital warts was observed in smoking patients caused by the immunosuppression caused by smoking [9,10].

Kaderli in a retrospective case-control study showed that smokers of more than 10 cigarettes a day have double the probability of having genital warts, it was additionally shown that both the incidence and recurrence of anogenital warts significantly increases. in smokers (Kaderli & Beat Challenge). Hansen in a longitudinal analysis showed that smoking patients had a 0.6% increase in the risk of being diagnosed with anogenital warts for each cigarette smoked daily (Hansen BT, Hagerup-). Drolet et al, 2019 in which it is evident that HIV is associated with the presence of high-risk HPV and multicentric lesions, also observing HPV persistence. Banura in a systematic review observed that HIV is a risk factor for anogenital warts in both men and women [11-14].

Another characteristic of this type of study is the effectiveness of treatment with Imiquimod, so we will discuss this topic in the next pages.

The study procedure manages to establish the problem under critical analysis and a sustained conceptual framework supported by medical and scientific evidence that undoubtedly leads to generalizations through systematic comparison between the characterizations of each of the articles, which allowed establishing relationships in statistical terms.

The object of study based on the Efficacy of Imiquimod determined highly satisfactory results, which generate a safe treatment that contributes to an important segment of patients who require this treatment and of course to solve a public health problem.

The sample of research and study articles gave way to knowing the sequence of methodological decisions during the investigative process, specifically pointing out the methods and procedures that jointly indicated the certainty of their application, predominating the characteristics and analysis. critical.

Therefore it is Concluded then:

Imiquimod has been shown to be a drug with good efficacy and safety in the treatment of HPV-related genital warts. With a new therapeutic approach based on immunomodulation. Requests were made three times a week for 10 weeks with a high complete response rate. Since the treatment is carried out by the patient himself and at home, the ease of application and low cost are of vital importance compared to other treatments and therapies. It becomes one of the best alternatives for the initial treatment for genital warts, less aggressive. The study clearly demonstrates the use of topical immunomodulators in the successful treatment of genital warts.

The benefits and harms of Imiquimod compared to placebo should be carefully considered due to the risk of bias, imprecision and inconsistency of many of the outcomes assessed in this Cochrane review. The evidence from many of the results showing that Imiquimod confers similar benefits, but that Imiquimod has fewer systemic reactions, is of low or very low quality. The quality of evidence for outcomes evaluating Imiquimod and other professionally administered treatments was of very low quality.

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