

*Full Length Research Paper*

## **Influence of speculum lubricants on cervical smears regarding pain relief and cytology results**

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**According with data collected cervical cancer is the 5th more frequent cancer in women and the 10th in the rank of all neoplastic diseases. From all malignant tumors, cervical cancer is the one best controlled by screening. The cervical smear is the more effective screening test on early detection of cervical cancer. The fear of pain or discomfort felt by the speculum's introduction may decrease adherence to screening, inducing physicians to use lubricants to minimize discomfort, and, increase the rate of screened women.**

**Keywords:** Cervical smear, lubricant, pain.

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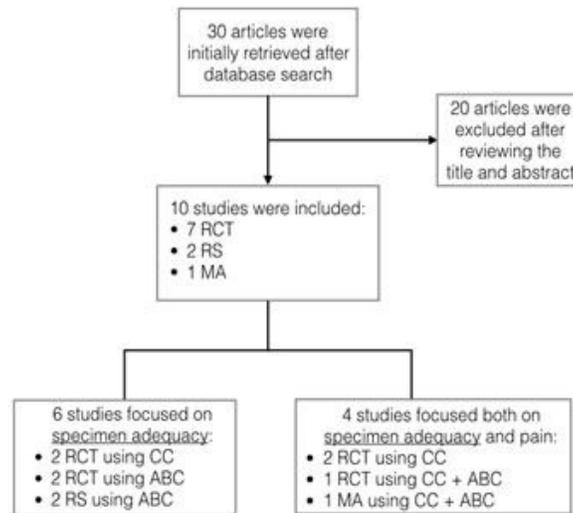
### **INTRODUCTION**

Cervical cancer is the 5th more frequent cancer in women and occupies the 10th place on the neoplastic disease ranking. (Doenças oncológicas 2014). Each year in Europe 34.000 new cases are diagnosed and over 16.000 result in death. (Arbyn et al.; 2010).

From all malignant tumors, cervical cancer is the one best screened, and its morbidity and mortality have decreased since the availability of the cytological screening provided by the Cervical Smear (CS). This affordable test allows for early detection of cervical cellular abnormalities and subsequent treatment,

preventing the development of cancer in the majority of cases. (Comprehensive Cervical Cancer Control 2014).

During 2013, in Portugal, 62,81% of women were screened for cervical cancer.<sup>1</sup> The number of women being screened can be impaired by the fear of pain/discomfort felt by speculum introduction. In an attempt to increase these rates, some physicians choose to use lubricants in order to make the examination less uncomfortable as possible. Nevertheless, some authors do not recommend the use of lubricants for they may alter the CS results.



**Figure 1** - Schematic representation of search strategy and final selection of included studies regarding focus and cytology type (RCT (Randomized controlled trials); RS (Retrospective Studies); MA (Meta-Analysis); OR (Odds Ratio); CI (Confidence Interval); EL (Evidence Level); CC (Conventional Cytology); ABC (Aqua Based Cytology))

(Holton et al., 2008, Charoenkwan et al., 2008, Köşüş et al., 2012).. Published guidelines, from the The Portuguese Northern Regional Administration of Health, on their manual for cervical cancer screening of 2009, advise against the use of lubricant for speculum introduction when collecting CS (Manual Executivo do Programa 2009).

Being the CS a cornerstone of preventive medicine, primary care physicians have a crucial role in improving screening rates, and promoting the degree of comfort for women during examination can constitute a health gain.

The goals of the present study were to evaluate the influence of lubricant use during CS on cytological results and to assess whether its employment provides relief from pain/discomfort felt during the speculum insertion.

## METHODS

Several databases, namely, Medline, National Guideline Clearinghouse, NHS, Canadian Medical Association Infobase, The Cochrane Library, DARE, Bandolier, TRIP and Index of Portuguese Medical Journals, were searched for published revision articles, meta-analysis, original studies and guidelines. Articles published between 2005 until July, 2015, written in English and/or Portuguese language, using the MeSH terms speculum, lubricants, vaginal smears and pain, were selected.

The outcomes investigated in the present review were the interference of lubrication use versus no lubrication during cervical cancer screening examination performed by CS on women and its impact on pain/discomfort relief was compared and evaluated.

The selected studies were ranked by Evidence level and Strength of Recommendation was assessed using the Strength of Recommendation Taxonomy (SORT) Scale from American Family Physicians. (Ebell et al., 2004).

## RESULTS

30 studies were found and 10 were selected, as **Figure 1** summarizes. The excluded studies have not fulfilled the inclusion criteria, were repeated articles or irrelevant to the studied question.

We attributed an Evidence Level (EL) of 1 to the studies Simavle S et al.10, Uygur D et al.11, Hathaway JK et al.12 and Griffith WF et al.13, for being randomized controlled trials with a small confidence interval (CI). The remaining 6 studies were ranked with an EL of 2.

According to Simavle10, a small amount of aqua based lubricant decreases pain felt by both pre and postmenopausal women, without significant effect on cytological results on conventional cytologies (CC). On their study, a small amount of aqua based lubricant was applied on the superior and inferior speculum surfaces of the experiment group, against a dry speculum on the control group. Besides cytological results, the pain was also assessed during examination in two moments, during introduction and opening of the speculum, two crucial moments during examination.

Uygur et al.11 applied an aqua based lubricant on the inferior portion of the speculum and realized two CS, one liquid based and a conventional one, on the experimentation group; on the control group, the speculum was lubricated with warm water and two CS.

**Table I** Representation of included studies evaluated for population, intervention and main conclusions.

	Author/ Year	Population (n)	Intervention	Conclusions	EL
<b>RCT</b>	Simavle S et al. 2014	1580	Control (dry speculum) vs Small amount of aqua-based lubricant Conventional cytology	Small amounts of aqua-based lubricant decreases pain felt by pre and postmenopausal women, without altering the quality of cytology results (p<0.001)	1
<b>RCT</b>	Uygur D et al. 2012	400	Aqua-based lubricant (K-Y® Jelly) vs Warm water Conventional and liquid-based cytology	Small amounts of aqua-based lubricant on the speculum do not interfere with cytological results (conventional or liquid-based) and decrease pain felt by postmenopausal women (p<0.05), but not in reproductive aged women (p<0.05)	1
<b>RCT</b>	Hathaway JK et al. 2006	200	Control vs contamination of sample with 0,5 ml of Surgilube® from the same woman Liquid-based cytology	Aqua based lubricants do not affect the results (CI 95%; 4,6 -12,1)	1
<b>RCT</b>	Griffith WF et al. 2005	3460	Aqua based lubricant vs water Conventional cytology	Small amounts of lubricant do not increase the rate of unsatisfactory results (OR 0.74;CI 95%; 0,41-1,35)	1
<b>RCT</b>	Holton T et al. 2008	110	No lubricant vs 0,1 - 0,5 g de K-Y® Jelly vs 0,1 - 0,5 g de Aquagel® Liquid-based cytology	Direct contamination of cytological samples with lubricant results in reduced cellularity (p<0.001)	2
<b>RCT</b>	Charoenkwan K et al. 2008	1334	Control vs cervix contamination with 1-1,5cm K-Y® Jelly, from the same woman Conventional cytology	Higher rate of unsatisfactory cytological results with lubricant use (p<0.01)	2
<b>RCT</b>	Gilson M et al. 2006	70	No lubricant vs 2,7g of aqua based lubricant Conventional cytology	Small amounts of lubricant do not affect cytology results (p=0.5) nor improves the discomfort felt during examination (p=0.69)	2
<b>RS</b>	Lin NS et al. 2014	3971	No lubricant vs carbomer free lubricant vs carbomer containing lubricant Aqua based cytology	Carbomer free lubricants do not affect specimen quality (OR=0,41, CI 95%=1,1-11, p=0.002); Lubricants containing carbomers decrease specimen adequacy (OR=30,3; CI 95%=16,6-55,1, p<0.0001)	2
<b>RS</b>	Kosus A et al. 2012	1999	Control vs aqua based lubricant Aqua based cytology	Higher rate of unsatisfactory results with lubricant use (p=0.01)	2
<b>MA</b>	Pergialiotis V et al. 2015	5 RCT e 2 quasi-Randomized Control Trials n=8717	Comparison of unsatisfactory results and pain relief with and without aqua based lubricants Conventional cytology	Speculum lubrication does not interfere with cytology result (OR=0,94; CI 95% = 0,64-1,37), nor relieves examination discomfort (OR=-0.37; CI 95% = -1.10-0.36)	2

RCT (Randomized controlled trials); RS (Retrospective Studies); MA (Meta-Analysis); OR (Odds Ratio); CI (Confidence Interval); EL (Evidence Level)

were collected, performing both CC and aqua-based cytology (ABC). Their work showed no effect on results interpretation from lubricant use, and a positive effect on pain reduction on postmenopausal women, not verified for women at reproductive age. The double blinded study conducted by Hathaway et al.<sup>12</sup> evaluated two ABC performed on each women, while 'contaminating' randomized samples with 0,5 mL of aqua-based lubricant

directly onto the brush on one of those samples. Although no effect on CS accuracy was found, the operated proceeding is not similar to current clinical practice.

Griffith<sup>13</sup> essay concluded that a small amount of lubricant plays no interference on cytological results, but SC were collected by different health professionals, with different degrees of professional experience, constituting an important bias when collecting unsatisfactory samples.

Holton and colleagues<sup>14</sup> concluded lubricant contamination on the ABC fluid might decrease samples cellularity. Regarding the methods, the authors applied directly on the liquid basis crescent amounts of 2 different lubricants (K-Y® Jelly e Aquagel®), and used the non-contaminated samples as controls. The interference with sample cellularity occurred for higher amounts of K-Y® Jelly (0,4 e 0,5g), and for Aquagel® at any given amount. Nevertheless, the biggest presented limitation is the reduced sample size on each group (10 CS for each group and lubricant amount).

Concerning the double blinded essay from Charoenkwan<sup>15</sup> concluded lubricant contamination of cervix might interfere with results from cytological analysis on conventional CS. Contamination occurred after collection, on the same woman, of a control sample (uncontaminated). Still, the adopted procedure is not similar to what is used in clinical practice.

Gilson and colleagues<sup>16</sup> collected two consecutive conventional CS from the same woman, one with dry speculum (control group) and another with 2,7g of aqua-based lubricant (case group). Results show speculum lubrication presents no effect CS results nor improves the discomfort degree during examination.

The retrospective study performed by Lin<sup>17</sup> reviewed the collected ABC smears performed by the Oncological Gynecology Unit from a hospital. Specimen adequacy was compared for CS were collected with and without lubricant. Type of lubricant was also registered (with and without carbomers). The authors concluded non-carbomer containing lubricants do not interfere with CS results, as opposed to carbomer containing ones, which compromise specimen adequacy. The study conducted by Kosus<sup>18</sup> is also a retrospective study based on ABC smear registrations on Fatih University Hospital in Ankara, recording use or not of aqua based lubricants. From the performed analysis, it was concluded that CS results are more accurate when lubricant is not used. Aqua based lubricant gel can be used in case of discomfort, informing women of possible result inaccuracy and potential need to repeat the CS. Limitations presented by the 2 aforementioned studies are attributed to the lack randomization or essay blindness.

The meta-analysis study from Pergialiotis<sup>19</sup> concludes lubrication of the speculum does not interfere with the conventional CS result, nor relieves the discomfort felt during examination. Studies included by this work present clinical and statistical heterogeneity, hence the attribution of EL 2.

## CONCLUSIONS

The studies included on the present evidence based revision are methodologically different, regarding examination technique and lubricant amount. Only one

study evaluated the employment of carbomer based lubricants, while the remaining ones chose aqua based lubricants.

Selected studies using a technique similar to clinical setting conclude aqua based lubricant use does not interfere with results nor alleviates discomfort felt during examination, except on postmenopausal women. We conclude a small amount of aqua based lubricant can be used, presenting no interference on CS results nor decrease discomfort during examination (Strength of recommendation A). Still, the evidence presented by the current study should not be understood as a general recommendation.

Further studies are needed, presenting more homogeneity, rigor, statistical power and proximity to clinical practice performance.

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