The use of Chaperone in Routine First Visit Examination of Women

Date: August 6, 2018.

1. Introduction

Guidelines for the presence of a chaperone, usually a female nurse, during intimate physical examination (eg, gynecological examination) vary according to country. In England, the General Medical Council recommends that all patients undergoing an intimate examination should be offered the possibility of an chaperone, irrespective of the gender of the patient or the gender of the physician (1, 2). In the United States, there is no national recommendation regarding the need for chaperones, and this recommendation is at the discretion of each state (3,4). Similarly, in Canada, the guidelines vary between provinces. For example, in Ontario there is the concept that both doctor and patient have the right to demand the presence of a third person during an intimate examination and, if necessary, insist that the examination be postponed if a third person is not present (5).

The use of chaperones depends, essentially, on the individual decision and preference of each doctor. In a study conducted in the United States, it was shown that male medical residents are more likely to use companions during a gynecological examination, but less likely to do so during breast examination or rectal examination. For female residents, the probability of using a chaperone was significantly lower. In addition, the use of chaperones during intimate exams performed in men was much lower than that seen in women (6).

In a similar study conducted in England, it was observed that 45% of general male clinicians never or rarely used chaperones in intimate examinations of women. Only 2% (3/178) of physicians used chaperones when examining men and only 8% of physicians did when examining women (7).

There are few studies, however, analyzing the patient's perception of whether or not a chaperones is needed. A study conducted in England attempted to evaluate patients' preference regarding this issue. Questionnaires on the subject were sent to men and women. A total of 190 men and 264 women answered these questionnaires. Of them, 15% were clearly opposed to the presence of companions, while 15% would like a chaperone to be present. The vast majority (59%) replied that they would feel uncomfortable if the chaperone was present without this being authorized by them. Most of the patientsthat did not wat a chaperone considered uncomfortable to have to be exposed to a third person during the examination, which would reduce confidentiality of the consultation and also the trust between doctor and patient (8). A similar study conducted in Australia, also through mail-in questionnaires, showed that more women would be more comfortable with the presence of a chaperone if the examining physician was male compared to the situation in which the physician was a female (31% vs. 14%, $P < 0.01$) (9).

Although the anorectal examination is part of the coloproctological routine, there is no published guideline regarding the need for the presence of a third person during this procedure. In addition, there is no publication so far evaluating the patients' perception of the need and adequacy of the presence of a chaperone during the proctological examination. What is seen in practice is that this decision of having a chaperone varies from doctor to doctor. In our Coloproctology Division, none of the physicians use to have a chaperone during the examination of female patients.

Considering the practical and legal implications of using a chaperone during the routine proctological examination, we propose a prospective study evaluating the perception of female patients regarding this issue.

2. Rationale

Although anorectal examination is part of the coloproctological routine, there is no guidance on the need for chaperone during the examination of female patients. Likewise, there is no study evaluating the patients' perception regarding the use or not of a chaperone during the proctological examination.

3. Objectives

3.1 General Objective:
To evaluate the degree of satisfaction of patients submitted to proctological examination with or without the presence of a chaperone.

3.2 Specific Objectives:
Correlate the degree of satisfaction of the patients with several clinical-demographic variables, including: age, marital status, diagnosis, comorbidities, symptomatology.

4. Hypotheses

Hypothesis 1: most patients will be satisfied without the presence of a chaperone during the anorectal examination.
Hypothesis 2: Most patients will be dissatisfied without the presence of a chaperone during the anorectal examination.

5. Materials and Methods

5.1 Study population

Adult women (18 years of age or older) who present for an initial consultation at our Coloproctology Division will be studied. These patients will be randomized into two groups:
1- Patients undergoing proctological examination with the presence of a chaperone.
2- Patients undergoing proctological examination without the presence of a chaperone.

The chaperone will always be a female, and may be a nurse or nursing assistant. Her participation will be communicated to the patient, who must agree to her presence during the proctological examination. After the consultation is completed, the patient will be informed that a study is being conducted and, if she agrees to participate, she should answer a specific questionnaire regarding the physical examination that was just performed. The purpose of the study will be explained, as well as the fact that participation is voluntary, not will change her clinical management, being guaranteed the secrecy and inviolability of the information obtained.

5.2 Exclusion Criteria

Refusal to participate in the study. Patients already under follow-up within our Division will not be included (only first visits). In addition, patients who undergo diagnostic or therapeutic procedures during the appointment (which is rare in first visit), such as hemorrhoid elastic ligation, will not be included in the study.

5.3. Primary Outcome Measure

The main outcome to be assessed will be patients' preference regarding the presence of a female chaperone during anorectal examination. It will also be assessed the degree of comfort (or embarrassment) according to the presence or not of a female chaperone during the proctological exam. This will be measured through a questionnaire compound of 6 questions (see Annexes 1 and 2). Each question will provide a isolated result (there will be no total score). The questions are the following:

1. How did you feel during the exam?
   Patients will register their answer in a scale from zero (completely embarrassed) to 10 (completely confortable)

2. What did you think of (not) having a person besides the doctor during the exam?
   Patients will have 3 possible answers: bad, indifferent, good.

3. Would you rather have taken the exam in the (without) presence of another person (woman)?
   There are 3 possible answers: yes, no, indifferent.

4. Do you think the (absence) presence of another person made the examination:

There are 3 possible answers: better, worse, did not change it.

5. Did you feel more (less) protected with (without) the presence of another person?
   There are 3 possible answers: yes, no, indifferent.

6. In the event of a reexamination, would you want another person's presence again?
   There are 3 possible answers: yes, no, indifferent.
   Or: Would you again like the doctor to examine you without another person's presence?
   There are 3 possible answers: yes, no, indifferent.

6. Ethical aspects

This research project follows the Normative Resolution 01/97 of the Commission for Research and Ethics in Health, as part of the Research Group and Post-graduation Prtogram/ HCPA. There will be no change in medical investigation and management whether or not the patient decide to participate in the study. The researchers garantee to preserve the privacy of patients whose data will be collected, to use this information solely and exclusively for the execution of this project and to publish the information obtained only anonymously.

7. Budget and sources of funding

There will be no additional cost to the HCPA with the completion of the study. The computer equipment and software required for data recording and its subsequent analysis are already available at our Division, and there is no need for new acquisitions or financing.

8. Sample size

The sample size was calculated based on a study conducted by Teague et al. (9), which showed that a larger number of women is more comfortable with the presence of a chaperone if the examining physician was a man, compared to the situation in which the examination was conducted by a female physician (31% vs. 14%, $P < 0.01$) (9). Using these differences, with 90% power and 0.05 error was estimated through the SPSS program, it would be required a total of 94 patients in each study group (with or without companion). Considering the volume of first visits attended in our Division of Coloproctology, it is estimated that the data collection will be completed in approximately two years.

9. Statistical Analysis Plan

Categorical variables will be described by absolute and relative frequency (percentage). The quantitative variables with symmetrical distribution will be described by the mean and standard deviation. Quantitative variables with asymmetric distribution will be described by median and interquartile range (percentiles 25 and 75). Chi-square or Chi-square tests with Yates correction will be used to compare the categorical variables. Quantitative variables with symmetrical distribution will be compared by the Student t test for independent samples. Quantitative variables with asymmetric distribution will be compared by the Mann-Whitney test. A level of statistical significance of 5% shall be considered in all tests used.

10. Cronogram of Activities

Date	Activities
January and February 2018	Elaboration, submission and approval of the research project
July 2018 to July 2020	Data collect
August to September 2020	Statistical analysis
October 2020	Bibliographic review and elaboration of the scientific article

12. References

1- The Royal College of Obstetricians and Gynaecologists. Gynaecological examinations, guidelines for specialist practice. London: RCOG, 2002.

2- Intimate Examinations. London, UK, General Medical Council. December 2001.

3- Gawande A: Naked. *N Engl J Med* 2005, 353(7):645-648.

4- Stagno SJ, Forster H, Belinson J: Medical and osteopathic boards' positions on chaperones during gynecologic examinations. *Obstet Gynecol* 1999, 94(3):352-354.

5- College of Physicians and Surgeons of Ontario: Avoid complaints of sexual abuse (policy document) [http://www.cpso.on.ca/Policies/avoid.htm].

6- Ehrenthal DB, Farber NJ, Collier VU, Aboff BM. Chaperone use by residents during pelvic, breast, testicular, and rectal exams. *J Gen Intern Med* 2000; 15(8): 573–576.

7- Conway S, Harvey I: Use and offering of chaperones by general practitioners: postal questionnaire survey in Norfolk. *Bmj* 2005, 330(7485):235-236.

8- Whitford DL, Karim M, Thompson G. Attitudes of patients towards the use of chaperones in primary care. *Br J Gen Pract* 2001;51:381-3.

9- Teague R, Newton D, Fairley CK, Hocking J, Pitts M, Bradshaw C, Chen M. The differing views of male and female patients toward chaperones for genital examinations in a sexual health setting. Sex Transm Dis. 2007; 34:1004.

Annex 1
Questionnaire - Patient with chaperone.

1. How did you feel during the exam?
Completely embarrassed Completely confortable
0_____10

2. What did you think of having a person besides the doctor during the exam?

Bad Indifferent Good
0_____5_____10

3. Would you rather have taken the exam without the presence of another person
Yes_____ No _____ Indifferent_____

4. Do you think the presence of another person made the examination:
Bether _____ Worse_____ Did not change it_____

5. Did you feel more protected with the presence of another person?
Yes_____ No _____ Indifferent_____

6. In the event of a reexamination, would you want another person's presence again?
Yes_____ No _____ Indifferent_____

Annex 2
Questionnaire - Patient without chaperone.

1. How did you feel during the exam?
Completely embarrassed Completely confortable
0_____10

2. What did you think of being examined by the doctor without another person present during the exam?
Poor Indifferent Good
0_____5_____10

3. Would you rather have taken the exam in the presence of another person (woman)?
Yes_____ No _____ Indifferent_____

4. Do you think the absence of another person made the examination:
Bether _____ Worse_____ Did not change_____

5. Did you feel less protected without the presence of another person?
Yes_____ No _____ Indifferent_____

6. In case of a new examination, would you again like the doctor to examine you without another person's presence?
Yes_____ No _____ Indifferent_____