

THE ADDED VALUE OF ULTRASOUND FOR THE DIAGNOSIS OF ECTOPIC PREGNANCY IN WOMEN OPERATED FOR LOWER ABDOMINAL PAIN.

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ABSTRACT

Background: Lower abdominal pain is a common complaint in women, occurring from 6% to 20% according to various studies. In USA, lower abdominal pain accounts for approximately 10% of outpatients in gynaecology consultation and is responsible for 10-35% of laparoscopies and 12% of hysterectomies performed.

Both clinical examination and ultrasound contribute to establish the diagnosis. However, the contribution of each is still unknown. Our hypothesis was that ultrasound is of paramount importance in the diagnosis of ectopic pregnancy. The objective of the study was to compare the value of ultrasound and clinical findings in ectopic pregnancy occurring in the context of lower abdominal pain.

Methodology: A prospective study was conducted from November 2001 to February 2002 in the department of gynecology and obstetrics of the national referral and teaching hospital in Kigali, Rwanda. We included fifty women who presented with lower abdominal pain and finally underwent surgery. Surgical results were compared to clinical and ultrasound findings for analysis.

Results: Among the fifty women included the commonest clinical diagnosis was ectopic pregnancy (18/50). Most patients did not present with the typical signs and symptoms. It was found that the ultrasound presented controversies: compared to clinical examination, the added value of ultrasound for ectopic pregnancy diagnosis was very low and sometimes negative.

Discussion: Lower abdominal pain is a symptom shared by many pathologies including ectopic pregnancy. For some pathologies, symptoms and clinical findings have high positive predictive value. This will lead to low added value of any other investigational procedure for the disease. Taken solely, ultrasound or clinical examination are not, in general, totally trustworthy.

Conclusion: In a setting with shortage of ultrasound skills, clinical findings should not be overruled by ultrasound. The latter can be a confirmatory test and not a systematic or specific one.

Keywords: Lower pain, ectopic pregnancy, ultra sound, added value

RÉSUMÉ

Introduction: Les douleurs abdominales basses constituent une plainte fréquente chez les femmes, allant de 6 à 20% selon différentes études. Aux Etats-Unis d'Amérique, ces douleurs se retrouvent chez environ 10% des patientes ambulantes en consultation de gynécologie et représentent 10 à 35 % des causes de laparoscopie ainsi que 12 % des hystérectomies.

L'examen clinique et l'échographie contribuent à l'établissement du diagnostic. Cependant la contribution réelle de chacune des deux méthodes diagnostiques reste inconnue. Notre hypothèse était que l'échographie a une plus haute valeur prédictive par rapport à l'examen clinique dans le diagnostic de la grossesse ectopique. L'objectif de l'étude était de comparer la valeur de l'échographie et de l'examen clinique dans le diagnostic de la grossesse ectopique survenant dans le cadre de douleurs abdomino-pelviennes.

Méthodes : Une étude prospective descriptive et analytique a été conduite de Novembre 2001 à Février 2002 dans le département de Gynécologie Obstétrique de l'hôpital national de référence «Centre Hospitalier Universitaire de Kigali», au Rwanda. Nous avons inclus dans l'étude cinquante patientes qui se sont présentées pour douleurs abdominales basses et ont subi une laparotomie. Les résultats per opératoires ont été confrontés à ceux de l'examen clinique et de l'échographie pour analyse.

Résultats : Parmi les cinquante patientes incluses, le diagnostic le plus fréquent était la grossesse ectopique (18/50). La plupart des patientes ne présentaient pas les symptômes ou les signes cliniques pathognomoniques. Nous avons trouvé que l'échographie pouvait être en contradiction avec l'examen clinique. Comparée à celui-ci, la valeur ajoutée de l'échographie dans le diagnostic de la grossesse ectopique, était non seulement faible mais parfois négative.

Discussion: Les douleurs abdominales basses font partie du tableau clinique de plusieurs pathologies dont la grossesse ectopique. Pour certaines pathologies, les symptômes et les résultats de l'examen clinique ont une valeur prédictive positive. Cela conduit à une réduction de la valeur ajoutée de toute autre procédure diagnostique pour cette pathologie. Pris séparément, ni l'examen clinique ni l'échographie, ne sont en général totalement fiables.

Conclusions: Dans un contexte de faibles ressources humaines qualifiées dans la pratique de l'échographie, cette dernière doit être un examen de confirmation et non l'examen de référence.

Mots-clés: Douleurs abdominales basses, grossesse extra-utérine, échographie, valeur ajoutée

BACKGROUND

Lower abdominal pain is a common complaint in women attending gynecological and obstetrical consultation.

It is part of many diseases whose frequency and characteristics are not known. In USA, lower abdominal pain accounts for approximately 10% of outpatients in a gynecology consultation and is responsible for 10-35%

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of laparoscopies and 12% of hysterectomies performed [1]. Lower abdominal pain in women is caused by a number of pathologies [2]: ectopic pregnancy, tubal ovarian abscess, uterine myoma, endometritis, molar pregnancy, ovarian cyst, incomplete abortion, pelvic inflammatory disease etc. Most of these causes of lower abdominal pain have similar signs and symptoms and the clinician has to exclude or confirm a diagnosis. The therapeutic decision is so important that the tools used in decision-making are worth being evaluated. It is for example needed to know the added value of some investigations such as ultrasound compared to clinical diagnosis in lower abdominal pain in general and in ectopic pregnancy in particular.

The objective of the study was to evaluate the added value of ultrasound compared to clinical findings for ectopic pregnancy, with surgery as gold standard in women presenting with lower abdominal pain.

METHODS

This prospective study was conducted from November 2001 to February 2002 in the department of gynecology and obstetrics, Central University Hospital of Kigali (CHUK).

During a period of 4 months all patients with lower abdominal pain who underwent a surgical intervention were included in the study. The symptoms and signs considered were severe pain, amenorrhea, vaginal bleeding, nausea, vomiting, pelvic mass, fever, chills

and discharge (pus). All patients have benefited of ultrasound. The decision to operate or not was taken during the staff meeting or with a senior doctor defined as one having been working in the department or similar service for at least 5 years. During this period of study, no patient in this category was operated before clinical and ultrasound data were obtained.

The ultrasound machine used was a Siemens model with a probe of 3.5 MHZ. The common surgical procedure was laparotomy. The value of any test was given by its positive and negative likelihood ratio (LR), and by its total discriminative value, the odds ratio (OR). Disease characteristics were supposed to be conditionally independent. Post-test probability was based on disease prevalence as given by the frequency of the surgical diagnosis in the sample, and positive or negative likelihood ratios of all related disease characteristics. The added value of ultrasound was calculated as the difference between the post-test probability obtained with clinical data and the final post-test probability [3,4,5]. EPI-info version 6.04 and Microsoft excel were used for analysis.

RESULTS

A total of fifty women were included. Median age was 31 years, mode 24 years. Fifty-one diagnoses were established as one patient was found with two diagnoses (ectopic pregnancy and pelvic inflammatory disease). Ectopic pregnancy was the commonest finding (18/51). (Table 1)

Table 1 : Frequency of diagnoses

Presumed diagnosis	Frequency	Percentage (%)
Ectopic pregnancy	18	35.3
Uterine myoma	17	33.3
Ovarian Tumor	11	21.6
Molar Pregnancy	3	5.9
Pelvic Inflammatory Disease	2	3.9
TOTAL	51	100%

The sensitivity and specificity of clinical findings and ultrasound for ectopic pregnancy are given in Table 2. Most patients had amenorrhea (sensitivity 99%) and nausea or vomiting (sensitivity 99%). They have also the highest overall discriminative power. Ultrasound had also a good sensitivity and specificity. No single clinical finding had a high specificity.

Post-test probability with clinical data alone, with clinical data and ultrasound, and the added value of ultrasound are shown in table 3. Ultrasound is most useful for the diagnosis of ovarian tumor. For the other diagnoses, its value is low, and most impressive, its value is negative for ectopic pregnancy! Combining all diagnoses, ultrasound has an added value of 7 percent.

Table 2: Characteristics for ectopic pregnancy

	Sensitivity	Specificity	Likelihood ratio positive	Likelihood ratio negative	OR
Severe pain	56	78	2,55	0,56	4,51
Vaginal bleeding	67	25	0,89	1,32	0,68
Amenorrhea	99	84	6,19	0,01	519,75
Pelvic mass	33	12	0,38	5,58	0,07
Fever or chills	5	84	0,31	1,13	0,28
Pus discharge	6	84	0,38	1,12	0,34
Nausea or vomiting	99	34	1,50	0,03	51,00
Ultrasound	89	84	5,56	0,13	42,48

Table 3: Added value for ultrasound to clinical diagnosis

Diagnosis	Probability with clinical data	Probability after ultrasound	Added value
Uterine myoma	93	100	7
Ectopic pregnancy	93	91	-2
Pelvic Inflammatory Disease	96	100	4
Ovarian tumor	51	98	21
Molar pregnancy	95	100	5
	85.6	97.8	7

DISCUSSION

General conclusion

This study in 50 patients in a national reference hospital in central Africa suggests that ultrasound has a good overall discriminative value, but a disappointing added value to clinical diagnosis in general; there is an added value for some specific diseases, where the present symptoms have a low specificity like ovarian tumor.

Objectives

One might question the value of suggesting a diagnosis when the decision to operate has already been made like in this study. Technically it might be interesting for incision, transfusion need, infection transmission risks etc.

The choice to investigate the added value is of utmost importance for developing countries, for the investment decisions, taking into account the opportunity cost: what is invested in ultrasound, can not be invested in other important needs for public health. Alas, very few studies concerning added value of paraclinical examinations have been organized.

Inclusion criteria

The choice of surgery as the inclusion criterion might have led to wrongly exclude some true cases, which healed spontaneously, went in chronicity, or were seen finally at another health facility. In future research, a

tight follow-up of all patients with abdominal pain should be organized.

Further, the clinician who examined the patient performed often the ultrasound, and made the decision to operate; hence there was no independence between clinical data, ultrasound and inclusion.

The most serious critic to this study might be that we evaluate the value of ultrasound, where it contributed itself to the decision to operate, hence to the inclusion criteria. However, this bias was dictated by the need of an unquestionable gold standard: surgery.

Methods

We focused our study of the added value on ectopic pregnancy because this condition is life threatening and often an emergency. For the other conditions, a second opinion, and a repeat ultrasound is often possible.

Some clinical data were not taken into account. Guarding is often referred to as crucial in the diagnosis of ectopic pregnancy, but its sensitivity is very low, and the definition differs from clinician to clinician. Laboratory data were not included since for ectopic pregnancy, the decision to operate is often taken before the results of the laboratory arrive; moreover, at the time of the study, several lab equipments were out of order, or not reliable.

If we concentrated on ultrasound, why did we not double check it? Or was it done by the most experienced echographer? Moreover, in several cases, the same clinician gathered the clinical data and performed the ultrasound, exposing to a serious bias of intentional thinking. First, there were organizational constraints precluding double check and independence of clinical data and ultrasound. Second, we wanted to simulate the real situation, not an ideal one, of which results are not applicable to day-to-day work.

Results

The small sample size and the short period of observation could have underestimated some pathologies.

How to explain that no single finding had a high specificity? False positives are made up by competing diseases and a background noise. While the latter remains stable during diagnostic work up, competing diseases become gradually more probable, and dilute the specificity for every competing diagnosis (waning specificity). In this case, this is enhanced by the choice of

the gold standard, selecting only operated patients.

This study concludes that the added value of ultrasound is low for ectopic pregnancy. This is because of the sufficient predictive power of clinical findings, but also because of some false negatives for ultrasound, explained by overlying bowel, or atypical images. However, we did not evaluate the added value in excluding the diagnosis. This analysis should be done in a cohort with both operated and not operated, but thoroughly followed patients, as we look for patients without the condition.

Literature

After a thorough literature search, no report was found that studies the added value of ultrasound.

In ectopic pregnancy vaginal bleeding was reported in 66.7%, while in the literature vaginal bleeding is reported in 75%. [6] For the diagnosis of ectopic pregnancy amenorrhea was present in 99%, which is very particular in our population, others reporting 75% [7,8]. It is known that Hartman's sign could mimic menstruation, and this has been brought forward to explain the not reporting of amenorrhea. We have no explanation why this sign is so rare. It is known that a good anamnesis can distinguish between Hartman's sign and a real menstruation. Some questions regarding the usual signs of previous periods should be asked: intensity of pain, duration, quantity etc. If some signs are not consistent, the bleeding might not be real menstruations.

Future research

Further studies, including a larger population and more than one site should be undertaken to determine the added value of ultrasound to clinical presentation in different pathologies. A cohort of patients with abdominal pain should be followed until operation or solving of the problem, with repeat consultations and ultrasound. Only in that way we can make definite conclusions about the discriminative value and added value of disease characteristics.

CONCLUSION

Clinical data alone allow a high post test probability for most causes of abdominal pain in patients ready for surgery, except for ovarian tumor. Although ultrasound has a very good overall discriminative value, its added

value is disappointing, and even negative for ectopic pregnancy. We conclude that clinical data should never be overruled by ultrasound in case of suspicion of ectopic pregnancy.

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